

**A STUDY TO ASSESS THE EFFECTIVENESS OF VAPOCOOLANT  
SPRAY ON REDUCTION OF PAIN AMONG CHILDREN OF AGE  
GROUP 1-5 YEARS UNDERGOING INTRAMUSCULAR  
INJECTION IN A SELECTED HOSPITAL  
AT COIMBATORE**

**By**

**Reg. No: 301216103**

**A DISSERTATION SUBMITTED TO THE TAMIL NADU  
Dr. M. G. R. MEDICAL UNIVERSITY, CHENNAI IN  
PARTIAL FULFILLMENT OF REQUIREMENT  
FOR THE DEGREE OF MASTER OF  
SCIENCE IN NURSING**

**APRIL 2014**

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**EXTERNAL**

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**INTERNAL**

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**APPROVED BY THE DISSERTATION COMMITTEE ON NOVEMBER 2012**

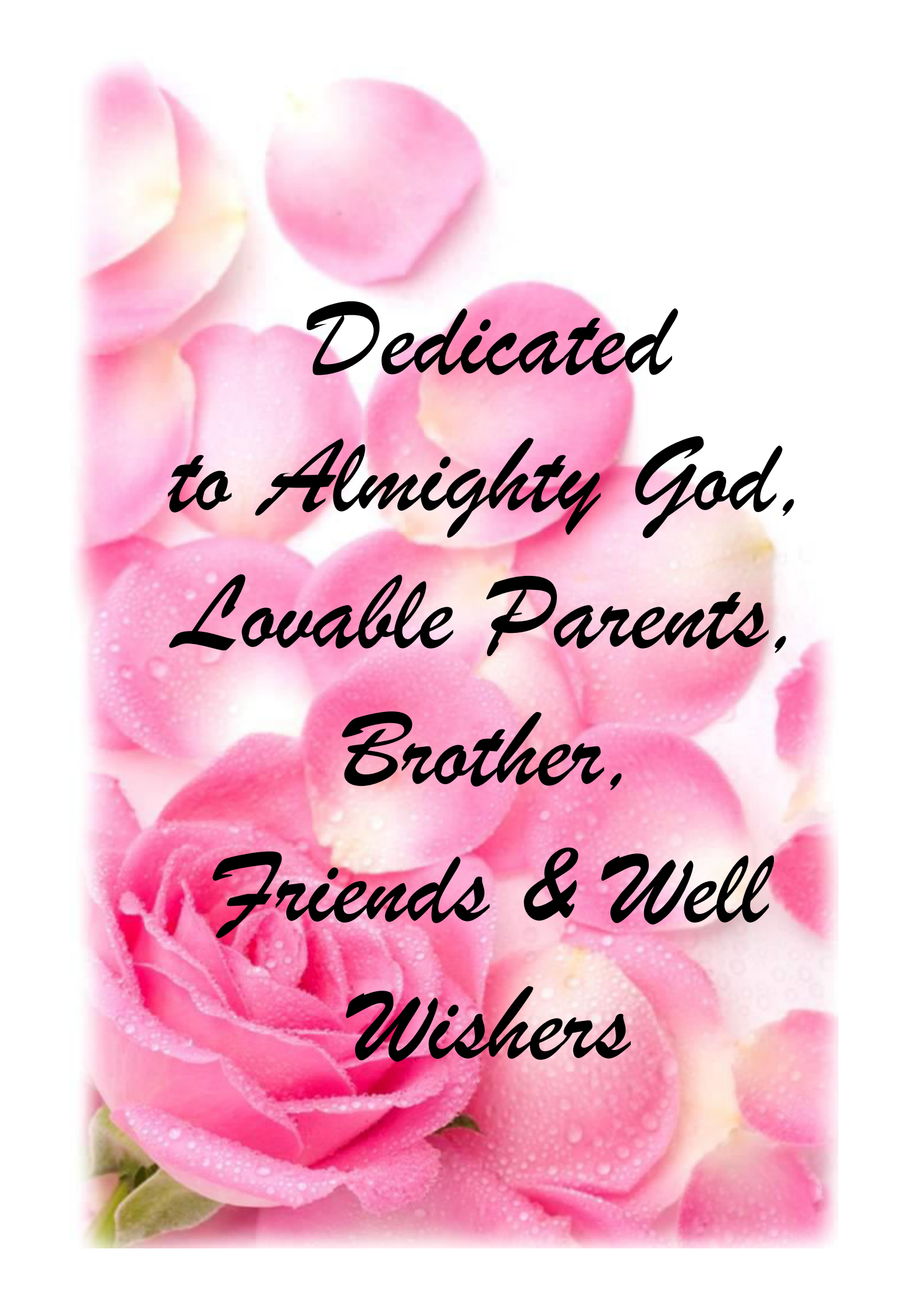
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The background of the image is a soft-focus photograph of pink roses and scattered petals. The petals are covered in small, glistening water droplets, giving them a fresh and delicate appearance. The colors range from light pink to a deeper magenta. The text is centered over this floral background.

*Dedicated  
to Almighty God,  
Lovable Parents,  
Brother,  
Friends & Well  
Wishers*

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# CHAPTER - I

## Introduction

*“Pain is temporary. Quitting lasts forever”*

*- Lance Armstrong, 2004*

Pain is a universal, complex and subjective experience. Pain is unpleasant feeling often caused by intense or damaging stimuli. The word pain comes from the Latin word ‘poena’ meaning fine or penalty. Pain has been identified as the fifth vital sign by Australian and New Zealand of anesthetics. It is very hard to forget pain. The Taxonomy committee of International Association for Study of Pain (IASP) defines pain as “an unpleasant sensory and emotional experience associated with actual or potential tissue damage”. Immunization distress also results in negative long-term outcomes (The International Association for Study of Pain, 2013).

Each individual learns the application of the word pain through experience related to injury in early life. For the child of any age, a visit to the hospital can be at best a frightening event and at worst a traumatizing experience. The children imagine hospital as a place, where they get injections. Injections of any kind can hurt, when they happen to see a nurse or a doctor with an injection syringe. The emotional disturbance and fears knows no boundary in children, who feel threatened by painful procedures (Neil.L.Schechter, 2012).

Help Eliminate Pain in Kids (2010) revealed that all children undergo routine immunization as a part of their medical care. Immunization injections are the most common source of iatrogenic pain in childhood, being administered repeatedly

throughout infancy, childhood and adolescence. Pain from vaccine injection is a source of distress for children, their parents and vaccinators and if not addressed can lead to pre-procedural anxiety at future procedures, early childhood experience with painful injection may lead to anxiety and fear. These reactions need not develop if steps are taken to reduce the pain associated with injections. Immunization distress also results in negative-long term outcomes.

Childhood immunizations are a priority for public health officials because the vaccinations benefit the child and the public. Children are inoculated against fatal illnesses and the public are protected from the spread of diseases. According to the Center for Disease Control and Prevention (CDC), children should receive approximately 28 inoculation injections before they are six years old. These routine and brief procedures provide protection against many infectious diseases, such as polio, measles, diphtheria, whooping cough, rubella, and mumps (Center for Disease Control and Prevention 2004).

Sorenson. M. (2002) stated that pharmacological and non-pharmacological means has been shown to be effective technique for managing pain in children. Distraction is effective if done correctly. It has been shown to be effective technique for managing pain in children. Topical anesthetic act by reversing inhibiting the generation and transmission of pain impulses across nerve ending located in the dermis. They decrease the pain as the needle penetrates the skin and reduce the underlying muscle spasm associated with this pain. Vapocoolant sprays provide transient skin anesthesia within seconds of application.

Herd. D. W. (2008) mentioned that failure to alleviate pain results in uncooperative child, unsuccessful procedures, prolonged procedure time and dissatisfaction with care for all involved. Toddlers and many school-age children experience high distress during immunization injections. Unfortunately, this procedure results in short- and long-term negative repercussions for the pediatric patient. The immediate impact is high levels of fear and anxiety spanning the whole medical visit and intense pain during and briefly following the immunization injection itself.

### **Need for the Study**

WHO (2013) mentioned that India is a vast country, where 26 million babies are born every year with world's second largest population. In 2011, the total number of children in the age group of 0-6 years is reported as 58.79 million. WHO statistics shows that probability of dying under five (per 1000 population) is 61. In India every year 3, 09,000 babies die on the first day of their birth. Millions of children below the age of 5 are at great risk of dying every year from easily preventable diseases. Nearly 1.2 million children under 1 year of age die every year due to largely treatable and even preventable diseases. The studies also showed over 55 percent children under the age of 2 years do not receive comprehensive routine immunization in India.

Children of today are citizens of tomorrow, which is why it is extremely important to ensure proper health care facilities as well as adequate nutritional intake for the children. Early childhood that is the first 6 years constitute the most crucial period in life. The children under 3 years is most vulnerable to the vicious cycles of diseases. India is one of those countries, where child mortality rate is alarming high.



Children contributes to one third of our population and all of our future, but unfortunately the gift of health which makes the child to be part of future is affected by so many diseases (Save the children, 2010).

WHO (2010) reports states that as a part of routine and specialized health care, children are subjected to a number of invasive medical procedures (eg: immunizations, venipunctures) and can have detrimental short-term and long term effects. According to guidelines published by the United States centers for disease control and prevention in 2005, children receive roughly 29 intramuscular immunization injection by 6 years of age. These events are anxiety provoking and painful especially for younger children, who exhibit higher distress than older children.

Children frequently undergo injection in the emergency department. This painful procedure causes considerable stress and anxiety for children and their parents. Immunization injections are the most common source of iatrogenic pain and leads to medical fears and health care avoidance behavior including non-adherence with immunization schedules. It is estimated that up to 25% of adults have needle fears. The majority of people with needle fears develop them in childhood. Efforts aimed at minimizing pain in childhood have the potential to prevent the development of needle fears and promote consumer satisfaction and trust in the health care system because of more positive experiences for children and their families (O.Quoba, 2005).

Todd Neale (2008) in his study revealed that early childhood experiences with painful injection may lead to anxiety and fear. These reactions need not develop, if

steps are taken to reduce the pain associated with injection. The development and administration of immunization are among the greatest public health achievements of the 20<sup>th</sup> century and their positive impact on disease prevention and reduction of human suffering is almost incalculable. Despite the proven benefit of these procedures, the pain associated with these injections is a source of distress for children and their family members.

Minimizing pain during childhood vaccination can help to prevent distress and promote trust in health care providers and high patient satisfaction. The IASP has observed the year 2005-2006 as “*the global year against pain in children*”. Assessing as well as managing pain is an important duty of nurse; they should work closely with the patient and family members without hurting their feelings and facilitating healing process. The nurses can use pain management interventions so as to relieve discomfort and pain in children and promote comfort to them (IASP-2005).

Kong. T. (2012) conducted a non-blinded, randomized controlled trial in 101 adult patients. The patients were randomized to one of three treatment groups. First group received vapocoolant spray, second group with cold alcohol swap stick and third group with alcohol swap stick stored at room temperature (control) and assessed the patient's pain after the arterial puncture using a 100-mm visual analogue scale. The study concluded that pretreatment using a cold alcohol swap stick as well as vapocoolant spray resulted in a decrease in patient's perception of pain associated with arterial puncture and facilitated the arterial puncture.

Elliot J. Krane (2008) said that children definitely do not perceive pain the same as adults do because, the emotional experience is very different. Even putting

aside the fact that there may be some chemical differences in the neuroanatomy and the neurophysiology of children, the way their central nervous systems act and behave compared to adults that changes the way pain is felt by their brains. They have a different emotional experience than do adults, and that emotional experience defines and drives how they experience pain.

Richards. R. N. (2009) conducted a study to assess the effectiveness of ethyl chloride medium-stream spray in reducing injection discomfort. Ethyl chloride medium-stream spray, in conjunction with precooling by frozen ice packs, in 51 consecutive cases of botulinum toxin injection was used. Ethyl chloride medium-stream spray, in conjunction with precooling by frozen ice packs, is highly effective in reducing painful injection sensations. Its use is safe, economical, and easy to learn and does not require special equipment.

Blount. R.L. et.al. (2001) conducted an observational study on pain among children of various age groups during venipuncture. 800 children from selected hospital at New York were included in the study. Pain was assessed by using various pain scales according to the age group. The study revealed that infants experience 50%, toddlers 30% and school age children experienced 20% of the pain. The study concluded that infants are the age group which experience high level of pain than other group.

Loyola University Chicago (2007) conducted a randomized controlled clinical trial to determine if before-hand application of topical ethyl chloride spray is more effective than placebo saline spray prior to intra- articular knee injections in patients of 18 years and older age group. Group A patients received a topical placebo (saline

spray) prior to their injection while those in Group B received topical anesthetic (ethyl chloride spray). Pain was assessed using the visual analog score (VAS) 100 mm scale. The study concluded that topical ethyl chloride spray may likely be safely administered prior to intraarticular knee injections to minimize pain related to the injection.

Shervin (2012) conducted a randomized double blind placebo-controlled trial to assess the effectiveness of Vapocoolant Spray on pain experienced by children of 14 years of age group and above in 80 subjects. Group one patients received a topical placebo (water spray) prior to their injection while those in Group two received topical anesthetic (ethyl chloride spray). The patient's pain was assessed using a 100-mm visual analogue scale and concluded that vapocoolant sprays provide transient skin anesthesia within seconds of application. Ethyl chloride spray resulted in a decrease in patients' perception of pain.

Therefore, from the above findings the researcher felt that there is a need to conduct the present study to assess the effectiveness of Vapocoolant spray in reduction of pain among children of age group 1-5 years and who is receiving intramuscular injection

### **Statement of the Problem**

A study to assess the effectiveness of Vapocoolant Spray on reduction of pain among children of age group 1-5 years undergoing intramuscular injection in a selected hospital at Coimbatore.

## **Objectives**

- To provide Vapocoolant spray before intramuscular injection to the experimental group.
- To assess the effectiveness of Vapocoolant spray during intramuscular injection among experimental group.
- To assess level of pain during intramuscular injection in control group.
- To compare the level of pain among experimental and control group.
- To associate the level of pain with selected demographic variables among experimental and control group.

## **Hypothesis**

H<sub>1</sub> There will be significant difference in the level of pain among children receiving IM injection between experimental and control group.

## **Operational Definitions**

### **Effectiveness**

Refers to the ability of the Vapocoolant spray in reducing pain as evidenced by difference in the score of experimental and control group.

### **Vapocoolant Spray**

It refers to the application of ethyl chloride spray on the injection site until the skin starts to turn white or numb prior to injection.

### **Pain**

An unpleasant sensory emotional disturbance experienced by children associated with IM injection, which is elicited by using FLACC scale.

**Children**

In this study, it refers to the children belonging to the age group of 1-5 years.

**Intramuscular Injection**

Refers to forcing of a liquid substances directly in to muscles.

**Assumption**

- Children are more prone to get pain during intramuscular injection.
- Vapocoolant spray reduces pain among children.

## **CHAPTER - II**

### **Review of Literature**

A research literature review is a written summary of the state of evidence on a research problem (Polit and Beck, 2011).

#### **The Related Review of Literature had Been Organized Under the Following Headings**

- Literature related to pharmacological modalities to reduce pain during injection.
- Literature related to non-pharmacological modalities to reduce pain during injection.
- Literature related to effectiveness of Vapocoolant spray in reduction of pain.

#### **Literature Related to Pharmacological Modalities to Reduce Pain during Injection**

Carol. Kahre et.al. (2011) performed randomized controlled trial to compare effects of pain relief during IV insertion using bacteriostatic normal saline and 1% buffered Lidocaine. The study compared the differences in the pain level experienced by 56 subjects during IV cannulation in each arm ; one premedicated with bacteriostatic normal saline (BNS) and another with 1% buffered Lidocaine (Lido). Subjects rated pain after each cannulation using a 0 to 10 verbal descriptor scale after IV cannulation was completed in both arms. Subjects were asked to reflect on which arm, and thus which type of preanalgesia, would be preferred if an IV is needed in the future. Although blinded to the type of preanalgesia used, 89% of subjects chose the arm premedicated with Lido.

Maj. P. Patterson et.al. (2000) compared pain on venipuncture, cost and convenience of 4 analgesic agents used for venipuncture. A convenience sample of 280 preoperative subjects was assigned randomly to 1 of 4 groups. Group 1 received 2.5% lidocaine - 2.5% prilocaine cream (LPC) topically, Group 2 received dichlorotetrafluoroethane spray (DCTF), Group 3 received 0.5% lidocaine subcutaneously and Group 4 received normal saline with 0.9% benzyl alcohol (BA) subcutaneously. A 7- point verbal descriptor scale measured pain on application and a 100mm visual analogue scale measured pain on venipuncture, cost was measured and compared on unit-dose basis, convenience was measured with a questionnaire survey and concluded that the 0.9% benzyl alcohol (BA) had all the qualities of an ideal analgesic agent for venipuncture.

Ostrow. C. L. (2004) synthesised reviews evidence for the use of eutectic mixture of local anesthetics (EMLA) cream to reduce the pain children experience during venipunctures. EMLA cream was compared with placebo, iontophoresis, and amethocaine cream and was found to be an effective local anesthetic for pediatric venipuncture pain during both intravenous cannulation and phlebotomy.

Speirs. A. F et.al. ( 2001) conducted a randomized, double-blind, placebo-controlled, comparative study of topical skin analgesics and the anxiety and discomfort associated with venous cannulation in 20 healthy volunteers. Skin application of either 4% amethocaine gel (Ametop), 5% eutectic mixture of Lidocaine and Prilocaine (EMLA) or E45 cream (placebo) were received by volunteer's undergoing venous cannulation. Visual analogue and verbal rating scales were used to assess pain and anxiety associated with the venous cannulation. The study concluded



that Ametop and EMLA topical anesthetic agents produce effective skin analgesia for venous cannulation.

Weltman. B. J. (2006) conducted a randomized controlled trials to compare the effectiveness of EMLA and amethocaine for relieving children's pain from intravenous cannulation or venipuncture. Six trials consisting of 534 children, three months to 15 years of age were included in this review. A meta-analysis was done for comparing amethocaine with EMLA on anesthetic efficacy, ease of needle procedure and resultant skin changes. For anesthetic efficacy, amethocaine significantly reduced the risk of pain compared to EMLA. A comparison of amethocaine and EMLA for ease of a needle procedure was not significant. For skin changes EMLA was favoured in the analysis of erythema. Erythema was observed after use of amethocaine whereas blanching was observed after using EMLA. Adverse effects included itching and one case of conjunctival irritation and concluded that although EMLA is an effective topical anesthetic for children, amethocaine is superior in preventing pain associated with needle procedures.

### **Literature Related to Non-pharmacological Modalities to Reduce Pain During Injection**

Chidambaram. A. G, et.al. (2013) conducted a cross over trial to assess the effect of KMC in reducing pain due to heel prick among preterm neonates. Premature infants pain profile (PIPP) related to heel prick was assessed in 50 preterm neonates undergoing KMC and compared with 50 preterm babies without KMC. The study revealed that KMC is effective in reducing pain due to heel prick among preterm babies.

Funda. K. Ozdemir, et.al. (2012) conducted a quasi experimental study in 120 healthy infants to assess the effect of using musical mobiles on reducing pain in infants during vaccination. FLACC was used to measure the level of pain. The study revealed that a lower pain score and shorter crying duration in response to vaccination in a room furnished with a musical mobile indicates that distraction via a musical mobile is a practical way to reduce pain during routine medical intervention in infants.

Hana Yoo. M. S, et.al. (2008) conducted an experimental study to evaluate the effectiveness of a distraction intervention (kaleidoscope) on pain response among 40 preschool children during venipuncture by using self reported pain responses and behavioral pain responses. A non equivalent control group pre test – post test quasi experimental design was used. The experimental group (20) was provided with distraction (kaleidoscope) and the control group (20) received standard treatment. The result showed that the distraction is effective and there were significant differences in self reported pain responses and behavioral pain responses among experimental group than in control group.

Khadijeh Boroumandfar, et.al. (2013) performed a randomized clinical trial study on 144 infants less than 6 months of age by convenience sampling to compare vaccine related pain in infants who receive Vapocoolant spray and breast feeding during injection. Data were gathered by questionnaire, check list and neonatal infant pain scale (NIPS). The study concluded that breast feeding during vaccination in infants under 6 months of age is effective, natural, safe, accessible and inexpensive method without side effects to reduce vaccine related pain.

Press. J, et.al. (2003) conducted an experimental study to evaluate the effects of active distraction (active listening to a song) during medical procedure. Ninety four (6-16 years) children were selected and they used visual analogue scale and pain threshold by dolorimeter. The study revealed that children receiving active distraction show less pain during venipuncture and was not time consuming.

Shah. V, Taddio, et.al. (2009) conducted a randomized control trial's and quasi randomized control trial's to assess the effectiveness and tolerability of various pharmacological and combined intervention for reducing pain experienced by children during immunization in 3856 (0-18 years) children. The study concluded that topical local anesthetics, sweet tasting solutions and combined analgesic intervention including breastfeeding were associated with decreased pain during childhood immunization and should be recommended for use in clinical practices.

Tufekei. F. G, et.al. (2009) conducted a study to assess the effect of distraction(looking through kaleidoscope) to reduce perceived pain during venipunctures in 206 children and rated by using Wong Baker Faces pain scale. The study concluded that the distraction made with kaleidoscope effectively reduced the pain related to venipunctures in healthy school children.

Yuanyuan Liang (2005) conducted a study related to effect of local cold therapy and distraction in pain relief using penicillin intra-muscular injection in children. 90 children ages from 5-12 who had penicillin injection intramuscularly in a health centre were studied. Samples were chosen randomly and divided into 3 groups. The first group received local cold therapy, the second group received distraction and

the third group (the control group) received routine care. The findings indicated that pain intensity was significantly higher in the control group than the experimental groups.

### **Literature Related to Effectiveness of Vapocoolant Spray in Reduction of Pain**

Daniil Polishchuk (2012) conducted a prospective, blinded, controlled study to investigate the sterility of ethyl chloride topical anesthetic spray applied before an injection. Fifteen healthy adult subjects were prepared for mock injections into both shoulders and both knees. Three culture samples were obtained from each site on the skin: one before skin preparation with isopropyl alcohol, one after skin preparation and before application of ethyl chloride, and one after ethyl chloride had been sprayed on the site. In addition, the sterility of the ethyl chloride was tested directly by inoculating cultures with spray from the bottles and concluded that although ethyl chloride spray is not sterile; its application did not alter the sterility of the injection sites in the shoulder and knee.

D. E. Page and D. Mc. D. Taylor (2010) conducted a non-blinded randomized controlled trial, in a large emergency department. Adult patients requiring IV cannulation were enrolled. They compared the efficacy, acceptability and safety of a topical Vapocoolant alkaline spray and 1% plain SC Lidocaine in reducing pain from IV cannulation for 110 patients by using visual analogue scale a 5 point likert scale. The study concluded that Vapocoolant reduces cannulation pain less than Lidocaine, but it is associated with great cannulation success, less time to administer and more staff convenience and median patient satisfaction.

Molloy (2006) conducted a randomized non-inferiority cross over trial comparing ethyl chloride with Ametop in 77 children (5 to 13 years) undergoing measurement of glomerular filtration. The study concluded that ethyl chloride is of equal preference to Ametop in children experiencing venipunctures, with lower self reported pain score; it should be considered as an alternative option to topical anesthetics.

Gonzalez (2000) conducted a study to evaluate the effectiveness of ethyl chloride application for local anesthesia during application of shock wave therapy at different level of energy in 578 patients. The study concluded that it is very useful and very comfortable for patients and avoid subcutaneous infiltration of local anesthetic and recommended as an alternative method in the local anesthesia in patients using shock wave therapy.

Celik, et.al. (2011) conducted a study to measure pain associated with venipunctures during AVF Cannulation to compare the effectiveness of Ethyl chloride Vapocoolant spray, topical eutectic mixture of local anesthetic (EMLA) cream and placebo in controlling pain by venipunctures in 41 patients undergoing hemodialysis. They used 0-10 mm visual analogue scale. The study concluded that the local application of EMLA is more effective in preventing venipunctures pain; Ethyl chloride Vapocoolant is as effective as EMLA for preventing mild to moderate puncture pain in patients undergoing hemodialysis.

Lindsey. L. Cohen (2009) done a study to assess the pharmacologic technique and non-pharmacologic technique for the management of procedure related pain in children. The study concluded that a variety of pharmacological strategies are

available for the management of pediatric procedural pain, EMLA is effective for venipunctures; but its efficacy in IM injection is limited and immediate effect preparation like ethyl chloride are time and cost effective ;but has equivocal efficacy and limited by their short duration of anesthetic effect.

Ken.J.Farion (2006) conducted a non-invasive pharmacological means of alleviating pain by double blind randomized controlled trial for 80 children (6-12 years). Children rated their pain using a 100mm, colour visual analogue scale. The researcher found a modest, but significant reduction in pain with the use of Vapocoolant spray and concluded that the Vapocoolant spray quickly and effectively reduce pain due to IV cannulation.

Kelishadi, et.al. (2013) conducted prospective randomized study in 15 subjects to apply Vapocoolant technology to facial rejuvenate to decrease pain associated with neurotoxin or filler injection. The study concluded that Vapocoolant spray decreases pain associated with facial rejuvenate procedures.

Mawhorter. S, et.al. (2004) studied the effectiveness of topical Vapocoolant on adult client at international travel clinic and adopted a randomized single blinded, placebo controlled study in 172 clients. The pain was measured by using a modified Mc Gill present pain intensity scale. The study revealed that Vapocoolant spray is an effective, quick, preferred and inexpensive agent for reducing vaccine associated pain for international travel clients.

## **Conceptual Framework**

Tolbot (1995) stated that conceptual framework is a network of inter related chances that provide a structure for organizing and describing the phenomenon of interest.

The conceptual framework for this present study was derived from Katherine Kolcaba's Theory of Comfort.

Kolcaba (1994) had defined comfort as the immediate state of being strengthened through having the human needs for relief, ease and transcendence. Kolcaba's theory components are

- Health care needs
- Comfort measures
- Intervening Variables
- Comfort
- Health seeking behaviors
- Institutional Integrity

## **Health Care Needs**

Kolcaba defines health care needs for comfort, arising from stressful health care situations that cannot be met by recipient's traditional support systems. Health deficits arising from stressful health care situations where the body fails to meet the demands. These needs include physical, social and environmental needs made apparent through monitoring and verbal or nonverbal reports, needs related to pathophysiological parameters, needs for education and support, needs for financial counseling and intervention.

In the present study, the need was to reduce the pain among children of age group 1-5 years undergoing Intramuscular injection. Pain was assessed through FLACC scale.

### **Comfort Measures**

Comfort measures are defined as nursing intervention designed to address specific comfort needs of recipients including physiological, social, financial, psychological, spiritual, environmental and physical intervention.

In the present study vapocoolant spray was provided to children of age group 1-5 years undergoing Intra muscular injection.

### **Intervening Variables**

Intervening variable are defined as interacting forces that influence recipient's perceptions of total comfort. This consists of variables such as past experiences, attitude, emotional state support system, prognosis, finances and the totality of elements in recipient's experience (Kolcaba, 1994).

In the study the intervening variables are age of the child, sex, education, occupation of father, occupation of mother, family income, number of children, birth order, religion, education of mother, education of father, area of residence, type of family, type of vaccine/injection.

### **Comfort**

Comfort is defined as the state that is experienced by recipients of comfort measures. It is the immediate and holistic experience of being strengthened



through having the needs met for three types of comfort (relief, ease and transcendence) in four context of experience (Physical, psychological, spiritual, social and environmental).

In the study the child's level of pain perception were reduced and are assessed through standardized FLACC scale.

### **Health Seeking Behaviors**

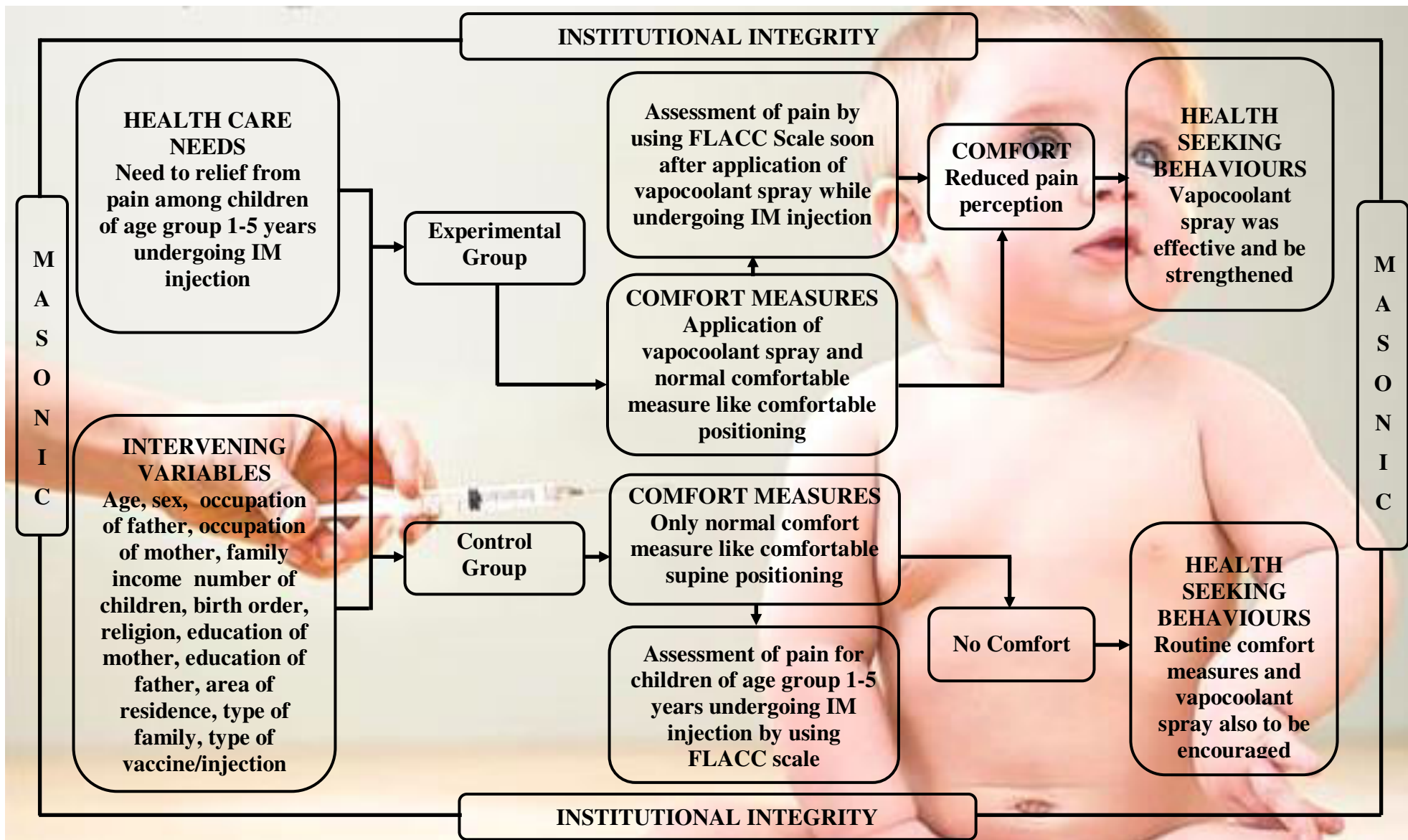
The Concept represents the broad category of subsequent outcomes related to the pursuit of health as defined by the recipient in consultation with the nurse.

In this present study children of age group 1-5 years undergoing IM injection pursuit in order to get relieved from pain perception.

### **Institutional Integrity (Masonic Hospital)**

Kolcaba (2001) provides the following technical definition of institutional integrity, corporations, communities, schools, hospitals, churches, reformities and so on, that possesses qualities or states of being, complete, whole, sound, upright, appealing, honest and sincere. The relationship between comfort and institutional integrity is recursive.

In the present study the hospital (Masonic) setting help children of age group 1-5 years undergoing IM injection to get vapocoolant spray for functioning its own value.



**Figure.1** Conceptual Framework Based on Modified Katherine Kolcaba's Theory of Comfort (1994)

## **CHAPTER- III**

### **Methodology**

This chapter deals with the methodology adopted by the researcher to assess the effectiveness of vapocoolant spray for reduction of pain among children of age group 1-5 years undergoing intramuscular injection in selected hospitals at Coimbatore.

In this chapter, the researcher discusses the research approach, research design, setting of the study, population, size of the sample, sampling technique, criteria for selection of the sample, description of tool, testing of tool, pilot study, data collection procedure and plan for data analysis.

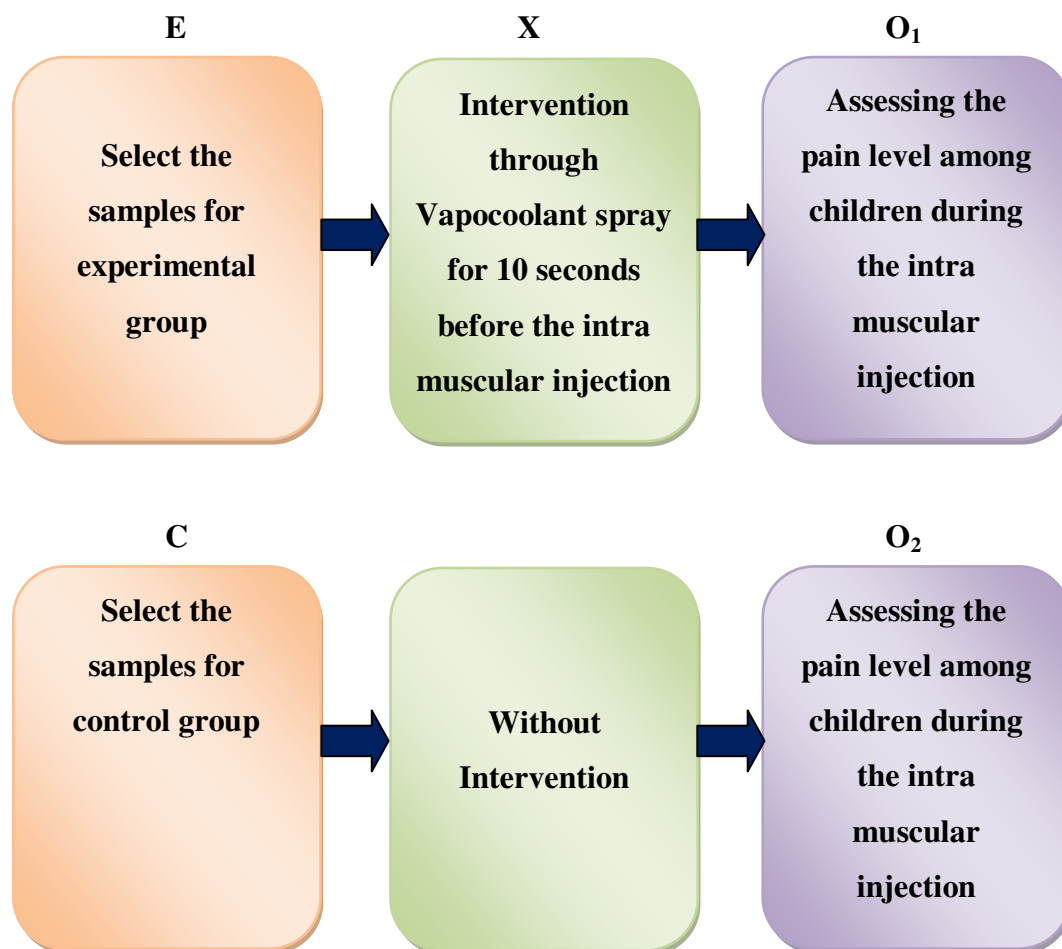
#### **Research Approach**

Quasi-experimental approach, a subtype of quantitative approach was used for the present study.

#### **Research Design**

The research design was post test only control group design.

- E      - Experimental group
- C      - Control group
- X      - Intervention in the form of vapocoolant spray
- O<sub>1</sub>    - Observation with intervention
- O<sub>2</sub>    - Observation without intervention



**Figure. 2 The Schematic Representation of the Research Design**

### **Setting of the Study**

This study was conducted among children of age group 1-5 years, who are undergoing intramuscular injection in Masonic Hospital at Coimbatore. It is a pediatric hospital situated 20 kms from college.

### **Variables**

Independent variable was intervention in the form of Vapocoolant spray. The dependent variable was pain among children. The influencing variables were demographic variables.



## **Criteria for the Selection of Samples**

### **Inclusive Criteria**

- Children within the age group of 1-5years.
- Children who are admitted in pediatric ward and receiving intramuscular injection in Masonic hospital, Coimbatore.
- Children who are receiving immunization through intramuscular route in Masonic hospital Coimbatore.
- Who are willing to participate in the study, and whose parents give consent to participate in the study

### **Exclusive Criteria**

- Terminally ill child
- Mentally retarded children
- Children who are having history of allergy towards the medication
- Asthmatic children

## **Description of the Tool**

The researcher has developed tool after reviewing the literature and considering the opinion of pediatric nursing experts, to assess the level of pain reduction after application of Vapocoolant spray for 10 seconds before to intramuscular injection.

### **Section - I            Description of the Demographic Variables**

The demographic variables includes age of the child, sex, education of the child, religion, education of father, education of mother, occupation of mother,

occupation of father, family income ,number of children in the family, birth order, area of residence, type of family, type of vaccination/injection.

## **Section - II          FLACC Scale**

The Face, Legs, Activity, Cry, Consolability scale or FLACC scale is a measurement tool used to assess pain for children between the ages of 2 months–7years or individuals who are unable to communicate their pain. The scale is scored between a range of 0–10 with 0 representing no pain. The scale has 5 criteria which are each assigned a score of 0, 1 or 2

### **FLACC Scale**

<b>Criteria</b>	<b>Score 0</b>	<b>Score 1</b>	<b>Score 2</b>
<b>Face</b>	No particular expression or smile	Occasional grimace or frown, withdrawn, uninterested	Frequent to constant quivering chin, clenched jaw
<b>Legs</b>	Normal position or relaxed	Uneasy, restless, tense	Kicking, or legs drawn up
<b>Activity</b>	Lying quietly, normal position, moves easily	Squirming, shifting back and forth, tense	Arched, rigid or jerking
<b>Cry</b>	No cry (awake or asleep)	Moans or whimpers; occasional complaint	Crying steadily, screams or sobs, frequent complaints

<b>Consolability</b>	Content, relaxed	Reassured by occasional touching, hugging or being talked to, distractible	Difficult to console or comfort
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The possible maximum score was 10

The possible minimum score was 0

### **Grading**

<b>Scores</b>	<b>Interpretations</b>
0	Relaxed and comfortable
1-3	Mild pain
4-6	Moderate pain
7-10	Severe pain

### **Testing of the Tool**

#### **Content Validity**

The tool was given to 6 experts in the field of pediatric nursing and medicine for content validity. All the comments and suggestions given by the experts were duly considered and corrections were made after discussion with research guide.

#### **Pilot Study**

In order to test the relevance and practicability of the study, a pilot study was conducted among 6 children in Masonic hospital Coimbatore, for a period of one



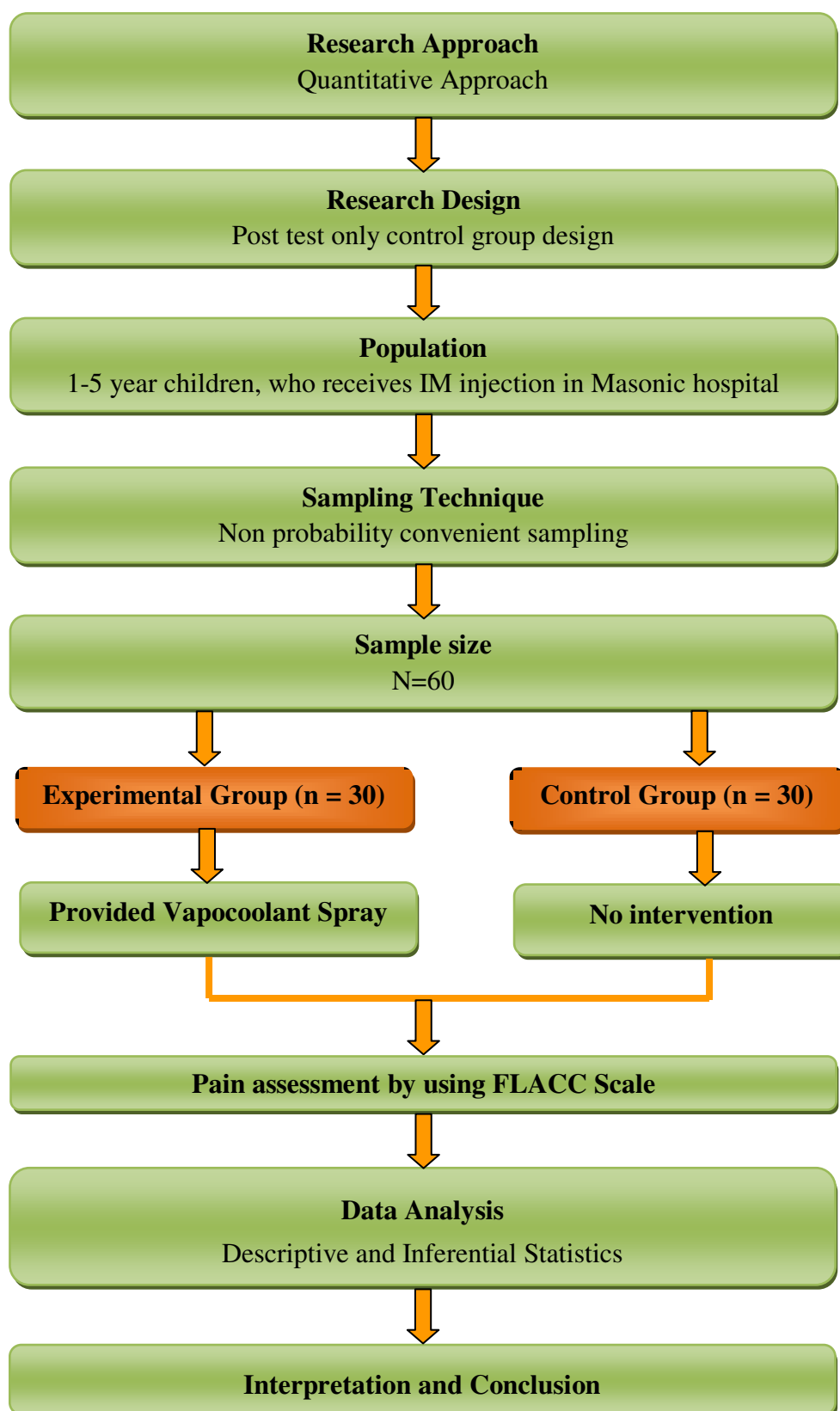
week. The effectiveness of Vapocoolant spray was assessed by using FLACC scale for 3 children in experimental group who received vapocoolant spray and 3 children in control group without intervention received standard care and positioning. The result of the pilot study showed that the Vapocoolant spray helped to decrease level of pain in children during intramuscular injection.

### **Data Collection Procedure**

After obtaining necessary permission from the concerned authorities and informed oral consent from the parents of children, the investigator collected data. The study was conducted for a period of 4 weeks from 01.07.13 to 31.07.13. The samples were selected by using non-probability convenient sampling technique. The data was collected from 6 children per day. It took 15 minutes to do the procedure. The samples were equally assigned to control and experimental group. The investigator assessed the pain of the child after IM injection. For the experimental group Vapocoolant spray was administered 10 seconds before the IM injection, and then the pain was assessed using FLACC scale. Children in control group were provided positioning and standard care during IM injection and pain was rated.

### **Plan for Data Analysis**

The data collected was analyzed by means of descriptive and inferential statistics. The demographic variables were analyzed by using frequency and percentage. The effectiveness of Vapocoolant spray in reduction of pain among children of age group 1-5 years and association between demographic variables were analyzed by using independent 't' test and  $\chi^2$  test respectively.



**Figure. 4** The Overall View of Research Methodology

## CHAPTER - IV

### Data Analysis and Interpretation

This chapter deals with analysis and interpretation of the data collected from the children of age group 1-5 years undergoing IM injection in selected hospital. The present study was designed to evaluate the effectiveness of Vapocoolant spray on reduction of pain among children of age group 1-5 years undergoing intramuscular injection in selected hospital at Coimbatore.

The findings based on the descriptive and inferential statistical analysis were presented under the following headings.

**Section I :** Distribution of demographic variables of experimental and control group of 1 -5 year age group children.

**Section II :** Distribution of statistical value of post test scores for experimental and control group regarding level of pain during IM injection among children of age group 1-5 years.

**Section III :** Comparison of pain level in experimental group and control group according to FLACC scale.

**Section IV :** Association of selected demographic variables with post test pain score of experimental and control group among 1-5 year of age group children.

## SECTION - I

**Table. 1** Distribution of Demographic Variables of Experimental Group and Control

Group of 1-5 Year Age Group of Children

(N = 60)

S.No.	Demographic Variables	Experimental Group (n = 30)		Control Group (n = 30)	
		f	%	f	%
1.	<b>Age in years</b>				
	a) 1-2 years	18	60%	15	50%
	b) 3-4 years	10	33%	11	37%
	c) 5 years	2	7%	4	13%
2.	<b>Sex</b>				
	a) Male	17	57%	16	53%
	b) Female	13	43%	14	47%
3.	<b>Education of child</b>				
	a) Nil	22	73%	24	80%
	b) Pre primary	8	27%	6	20%
4.	<b>Religion</b>				
	a) Hindu	26	87%	26	87%
	b) Christian	3	10%	2	6.5%
	c) Muslim	1	3%	2	6.5%
5.	<b>Education of father</b>				
	a) Illiterate	0	0%	0	0%
	b) Primary school	0	0%	2	6.5%
	c) High school	2	7%	5	16.5%
	d) Post high school/ Diploma	13	43%	6	20%
	e) Graduate	15	50%	17	57%

(Table 1 continues)

(Table 1 continued)

S.No.	Demographic Variables	Experimental Group (n = 30)		Control Group (n = 30)	
		f	%	f	%
6.	<b>Education of mother</b>				
	a) Illiterate	0	0%	0	0%
	b) Primary school	0	0%	2	7%
	c) High school	7	23.3%	10	33%
	d) Post high school/ Diploma	7	23.3%	7	23%
	e) Graduate	16	53.4%	11	37%
7.	<b>Occupation of father</b>				
	a) Professional	8	27%	5	16.7%
	b) Clerical	7	23%	8	26.6%
	c) Skilled	14	47%	12	40%
	d) Semi-skilled	1	3%	5	16.7%
	e) Unemployed	0	0%	0	0%
8.	<b>Occupation of mother</b>				
	a) Professional	7	23%	2	7%
	b) Clerical	3	10%	1	3%
	c) Skilled	4	13%	5	17%
	d) Semi-skilled	2	7%	3	10%
	e) Unemployed	14	47%	19	63%
9.	<b>Family income</b>				
	a) Below ₹.5000/-	0	0%	0	0%
	b) ₹.5001-10,000/-	3	10%	4	13%
	c) ₹.10,001-20,000/-	14	47%	12	40%
	d) ₹.20,001 and above	13	43%	14	47%

(Table 1 continues)

(Table 1 continued)

S.No.	Demographic Variables	Experimental Group (n = 30)		Control Group (n = 30)	
		f	%	f	%
10.	<b>Number of children in the family</b>				
	a) 1	17	57%	14	47%
	b) 2	12	40%	13	43%
	c) 3 and above	1	3%	3	10%
11.	<b>Birth order</b>				
	a) First	17	57%	14	47%
	b) Second	12	40%	13	43%
	c) Third and above	1	3%	3	10%
12.	<b>Area of residence</b>				
	a) Rural	12	40%	19	63%
	b) Urban	18	60%	11	37%
13.	<b>Type of family</b>				
	a) Nuclear	23	77%	22	73%
	b) Joint	7	23%	8	27%
14.	<b>Type of vaccine/injection</b>				
	a) DPT	7	23%	7	23%
	b) Hepatitis	6	20%	5	17%
	c) MMR	5	17%	2	7%
	d) Typhoid	7	23%	7	23%
	e) Others	5	17%	9	30%

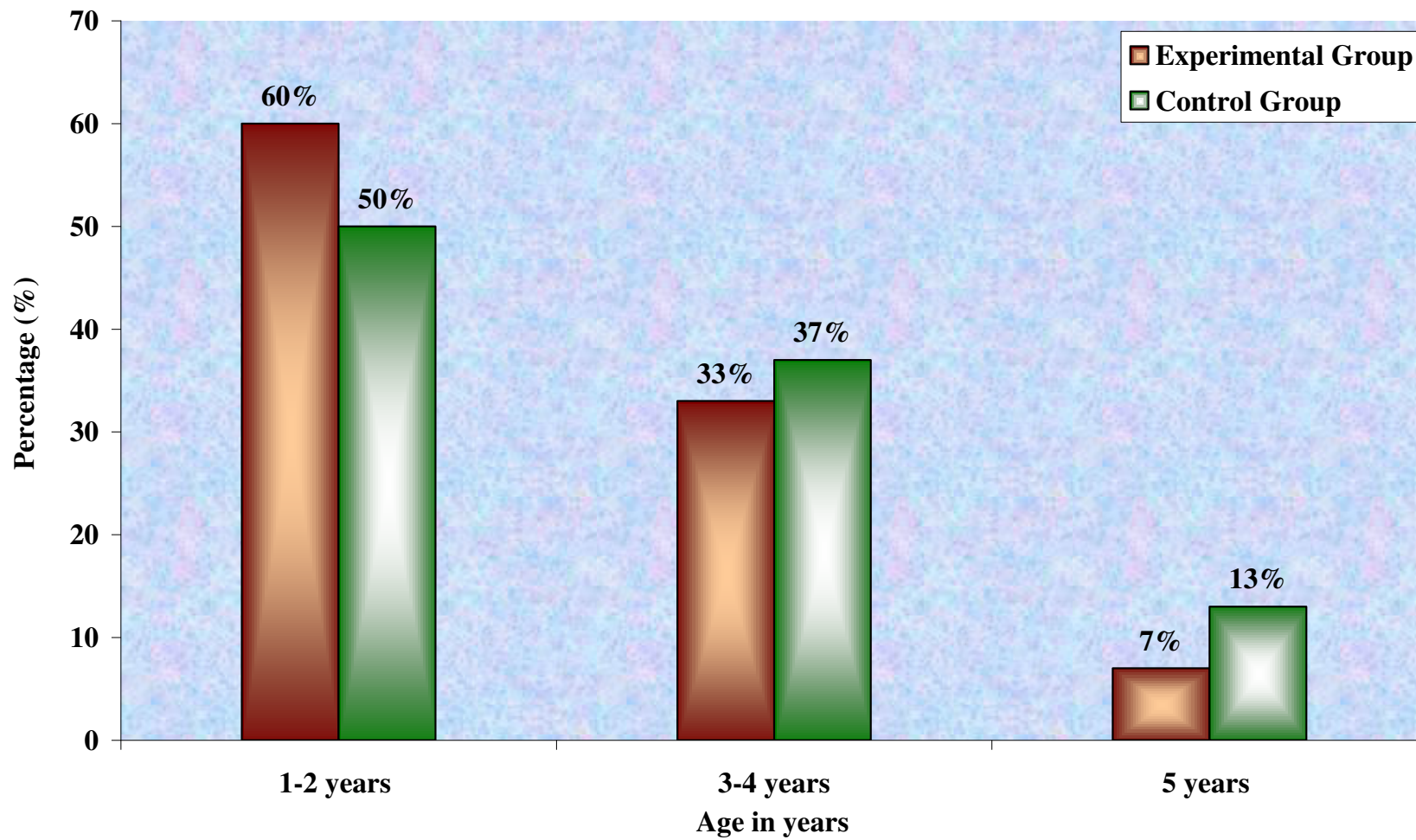
Table 1 shows Distribution of Demographic Variables in Experimental group and control group.

- Among the respondents in experimental group 18 (60%) were between age 1-2 years, 10(33%) were in the age group of 3-4 years, and 2(7%) were in the age group of 5 years.
- Among the respondents in control group 15 (50%) were between age 1-2 years, 11(37%) were in the age group of 3-4 years, and 4(13%) were in the age group of 5 years.
- Regarding sex, in experimental group 17 (57%) were male and 13(43%) were females.
- Regarding sex, in control group 16 (53%) were male and 14(47%) were females.
- With regards to education of child, in experimental group 22 (73%) were not educated and 8 (27%) were having preprimary education.
- With regards to education of child, in control group 24 (80%) were not educated and 6 (20%) were having preprimary education.
- Among the respondents, in experimental group 26 (87%) were Hindus, 1 (3%) were Muslims and 3 (10%) were Christians.
- Among the respondents, in control group 26 (87%) were Hindus, 2 (6.5%) were Muslims and 2 (6.5%) were Christians.
- About the education of father, in experimental group 0(0%) were illiterate, 0(0%) were primary school level, 2(7%) were high school level, 13(43%) were post high school level and 15(50%) were graduate.
- About the education of father, in control group 0(0%) were illiterate, 2(6.5%) were primary school level, 5(16.5%) were high school level, 6(20%) were post high school level and 17(57%) were graduate.

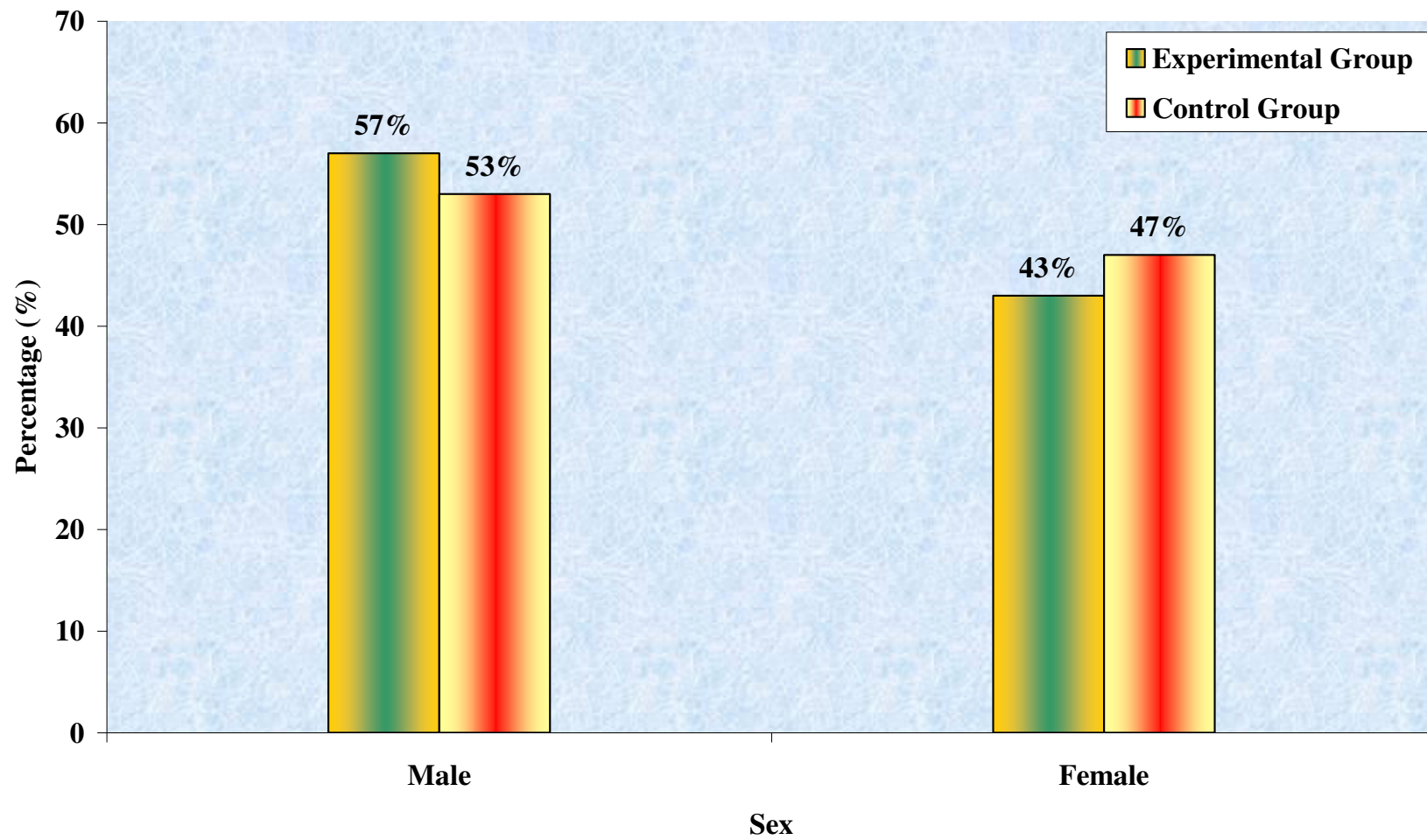
- With regards to education of mother, in experimental group 0(0%) were illiterate, 0(0%) were primary school level, 7(23.3%) were high school level, 7(23.3%) were post high school level and 16(53.4%) were graduate.
- With regards to education of mother, in control group 0(0%) were illiterate, 2(7%) were primary school level, 10(33%) were high school level, 7(23%) were post high school level and 11(37%) were graduate.
- Based on occupation of father, in experimental group 8 (27%) were professional, 7 (23%) were clerical, 14(47%) were skilled, 1(3%) were semi-skilled and 0(0%) were unemployed.
- Based on occupation of father, in control group 5 (16.7%) were professional, 8 (26.6%) were clerical, 12(40%) were skilled, 5(16.7%) were semi-skilled and 0(0%) were unemployed.
- In consideration to occupation of mother, in experimental group 7 (23%) were professional, 3 (10%) were clerical, 4(13%) were skilled, 2(7%) were semi-skilled and 14(47%) were unemployed.
- In consideration to occupation of mother, in control group 2 (7%) were professional, 1 (3%) were clerical, 5(17%) were skilled, 3(10%) were semi-skilled and 19(63%) were unemployed.
- Regarding total income per month, in experimental group 0(0%) were below ₹.5000, 3(10%) were between ₹.5001-10,000, 14(47%) were between ₹. 10,001 to ₹. 20,000 and 13(43%) were above ₹. 20,001.
- Regarding total income per month, in control group 0(0%) were below ₹. 5000, 4 (13%) were between ₹. 5001- 10,000, 12(40%) were between ₹.10,001 to 20,000 and 14(47%) were above ₹. 20,001.



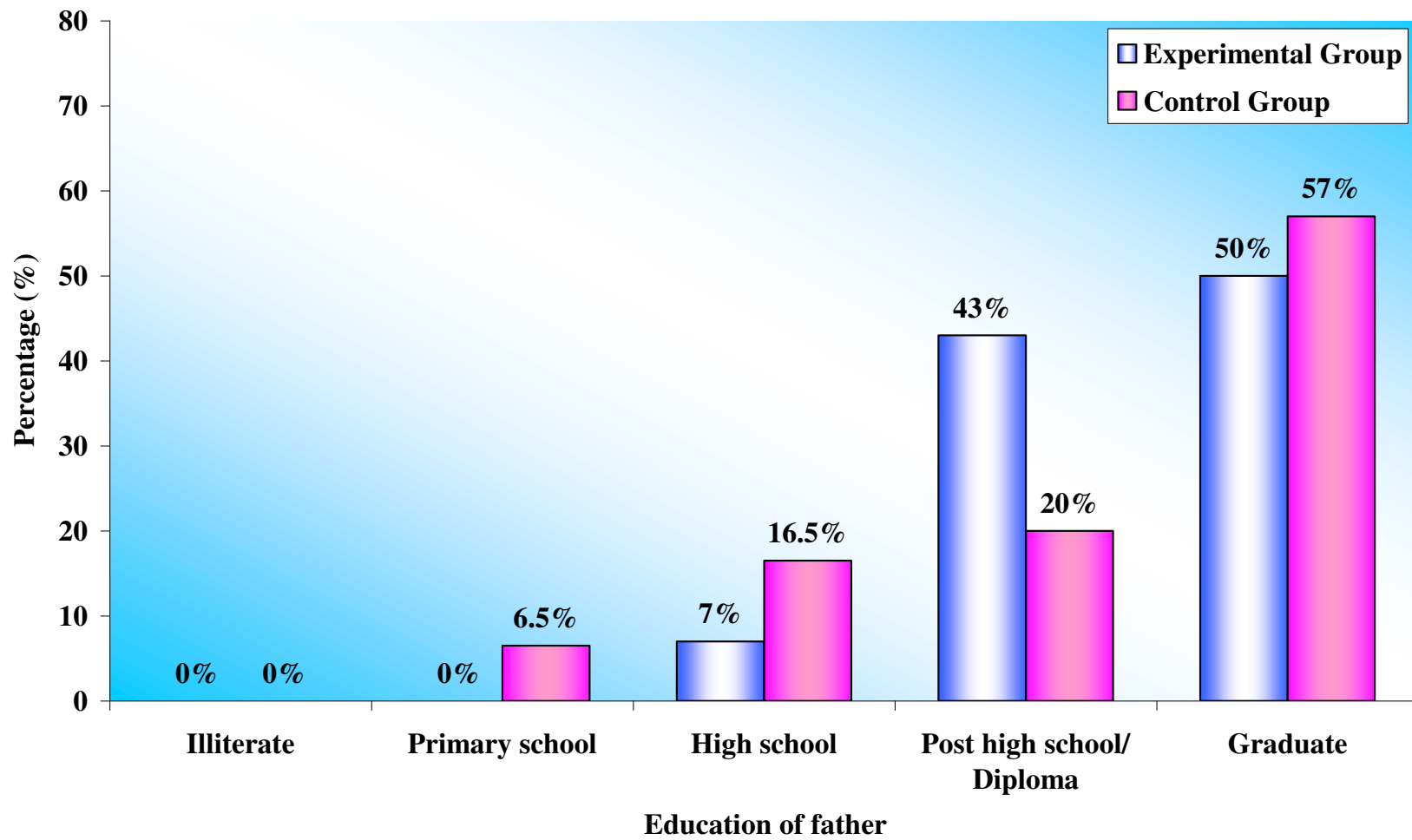
- With regard to number of children, in experimental group in a family 17(57%) were one child and 12(40%) were two child and 1(3%) were three and above.
- With regard to number of children, in control group in a family 14(47%) were one child, 13(43%) were 2 children and 3(10%) were 3 and above.
- Based on birth order, in experimental group 17 (57%) were first order child, 12(40%) were second order and 1(3%) were third order and above.
- Based on birth order, in control group 14 (47%) were first order child, 13(43%) were second order and 3(10%) were third order and above.
- Regarding residential area, in experimental group 12 (40%) were rural and 18(60%) were urban.
- Regarding residential area, in control group 19 (63%) were rural and 11(37%) were urban.
- About the type of family, in experimental group 23 (77%) were nuclear family and 7(23%) belong to joint family.
- About the type of family, in control group 22 (73%) were nuclear family and 8(27%) belong to joint family.
- About the type of vaccination/injection, in experimental group 7(23%) were DPT vaccine, 6(20%) were hepatitis vaccine, 5(17%) were MMR vaccine, 7(23%) were typhoid and 5(17%) were other vaccines/injection.
- About the type of vaccination/injection, in control group 7(23%) were DPT vaccine, 5(17%) were hepatitis vaccine, 2(7%) were MMR vaccine, 7(23%) were typhoid and 9(30%) were other vaccines/injection.



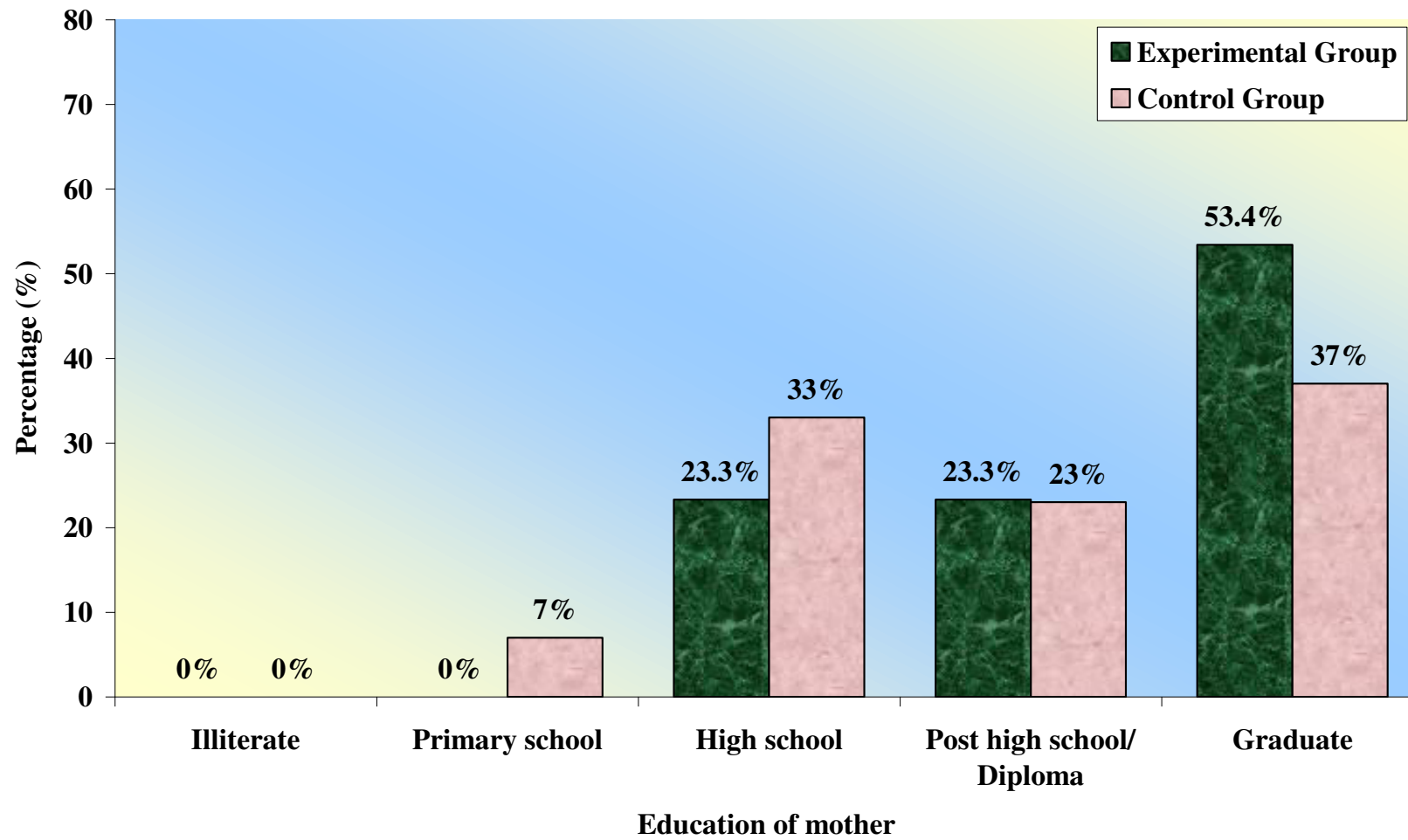
**Figure. 5** Distribution of Demographic Variables According to Age of the Child in Years



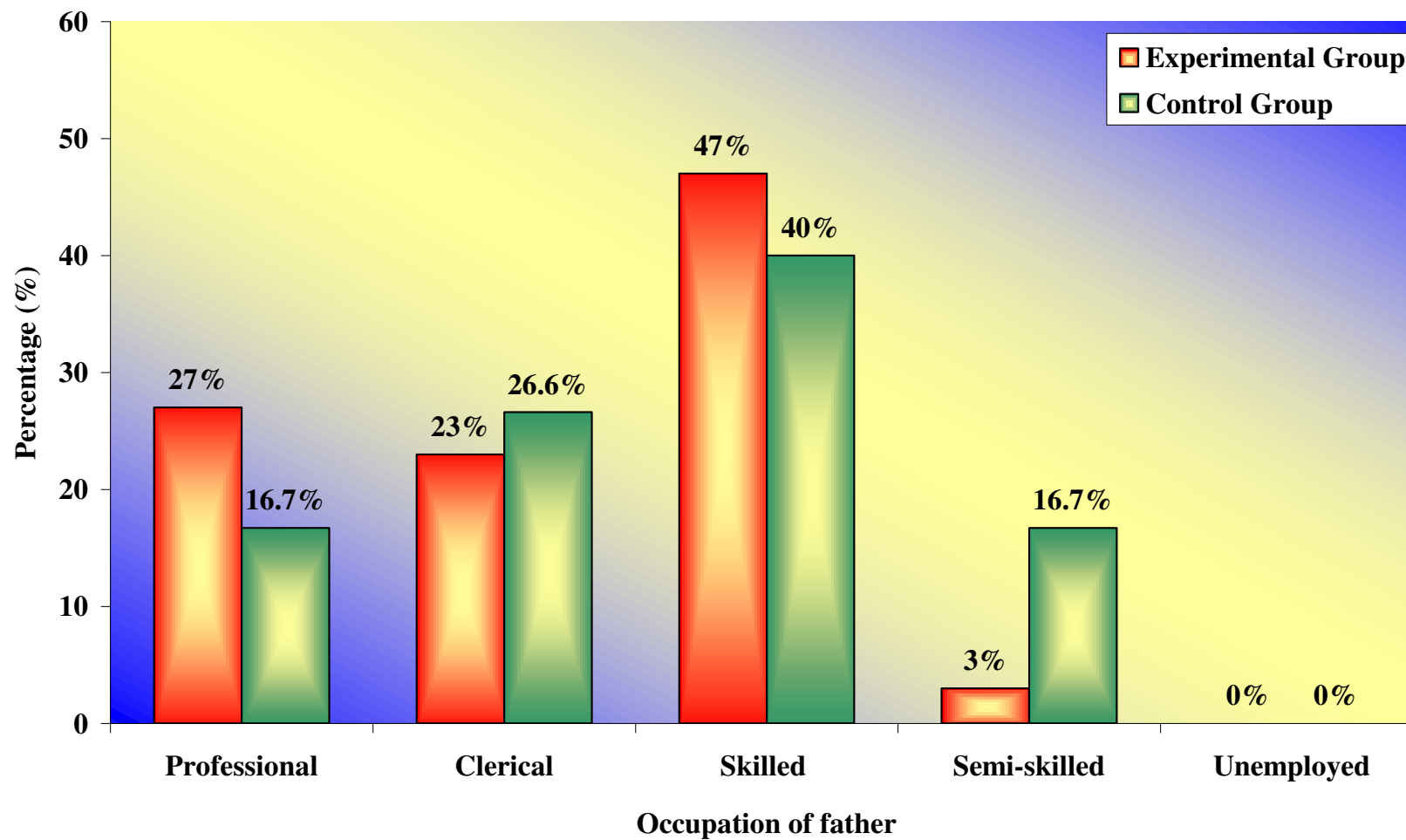
**Figure. 6** Distribution of Demographic Variables According to Sex of the Child



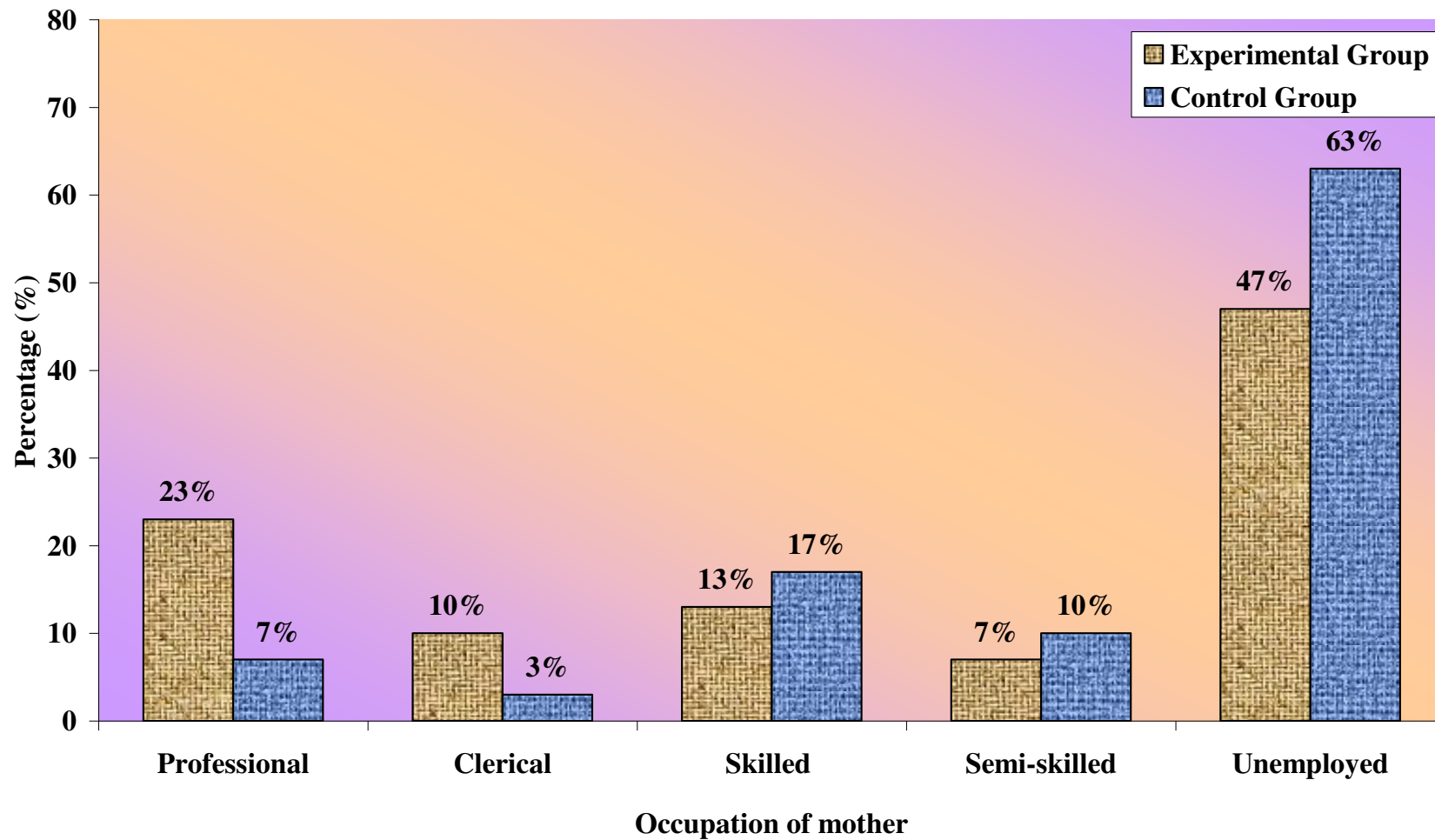
**Figure. 7** Distribution of Demographic Variables According to Education of Father



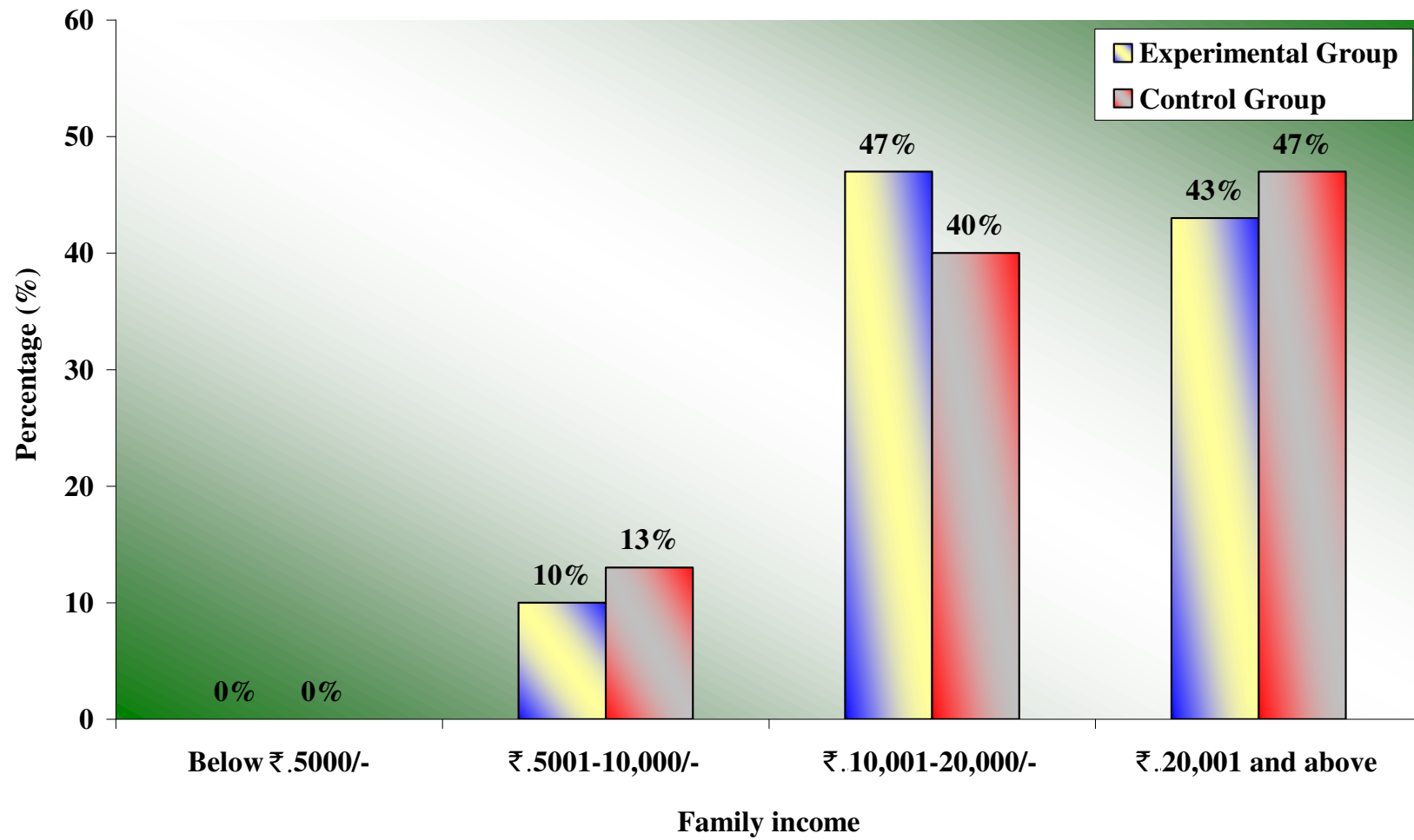
**Figure. 8 Distribution of Demographic Variables According to Education of Mother**



**Figure. 9** Distribution of Demographic Variables According to Occupation of Father

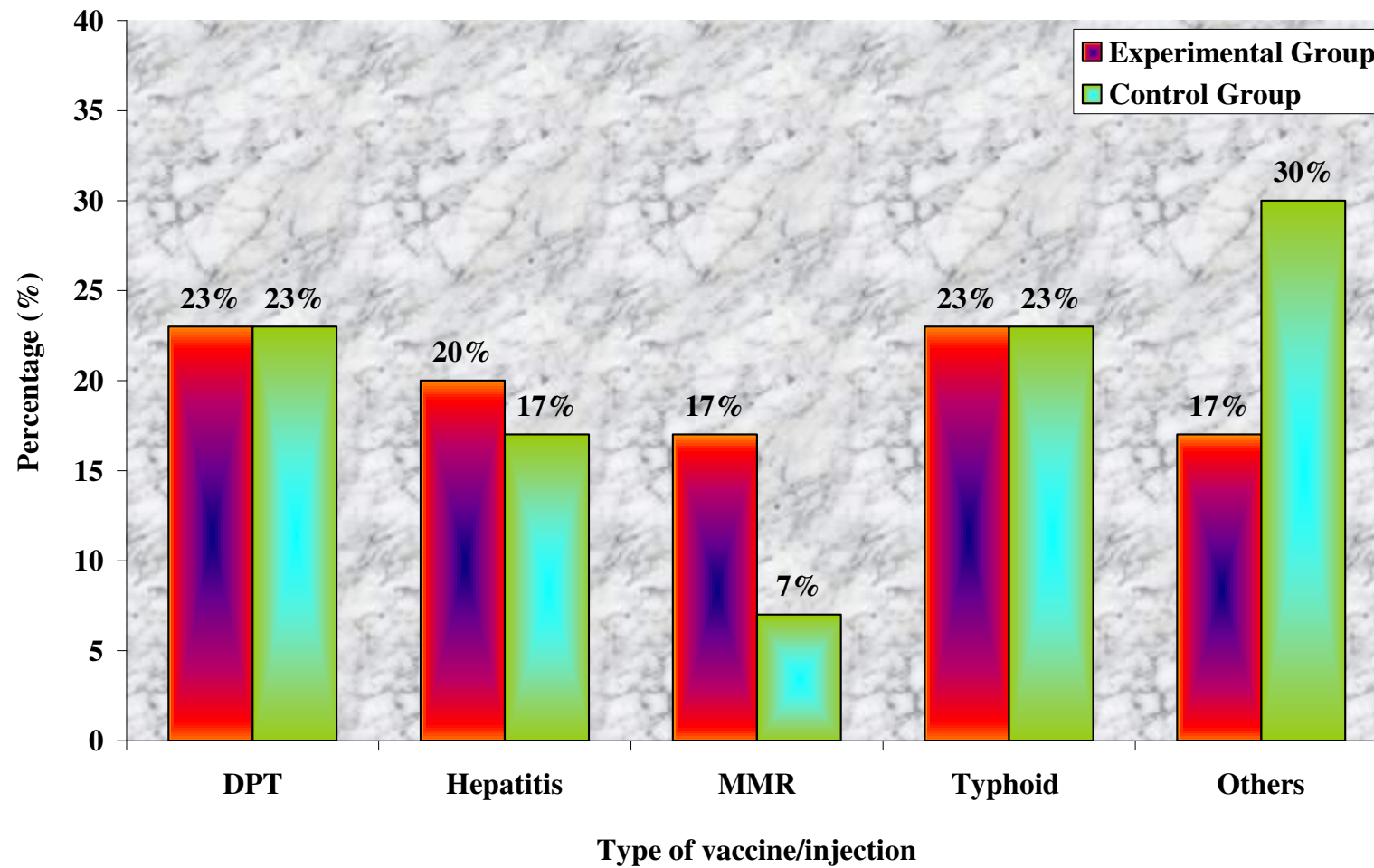


**Figure. 10 Distribution of Demographic Variables According to Occupation of Mother**



**Figure. 11** Distribution of Demographic Variables According to Family Income





**Figure. 12** Distribution of Demographic Variables According to Type of Vaccination

## SECTION - II

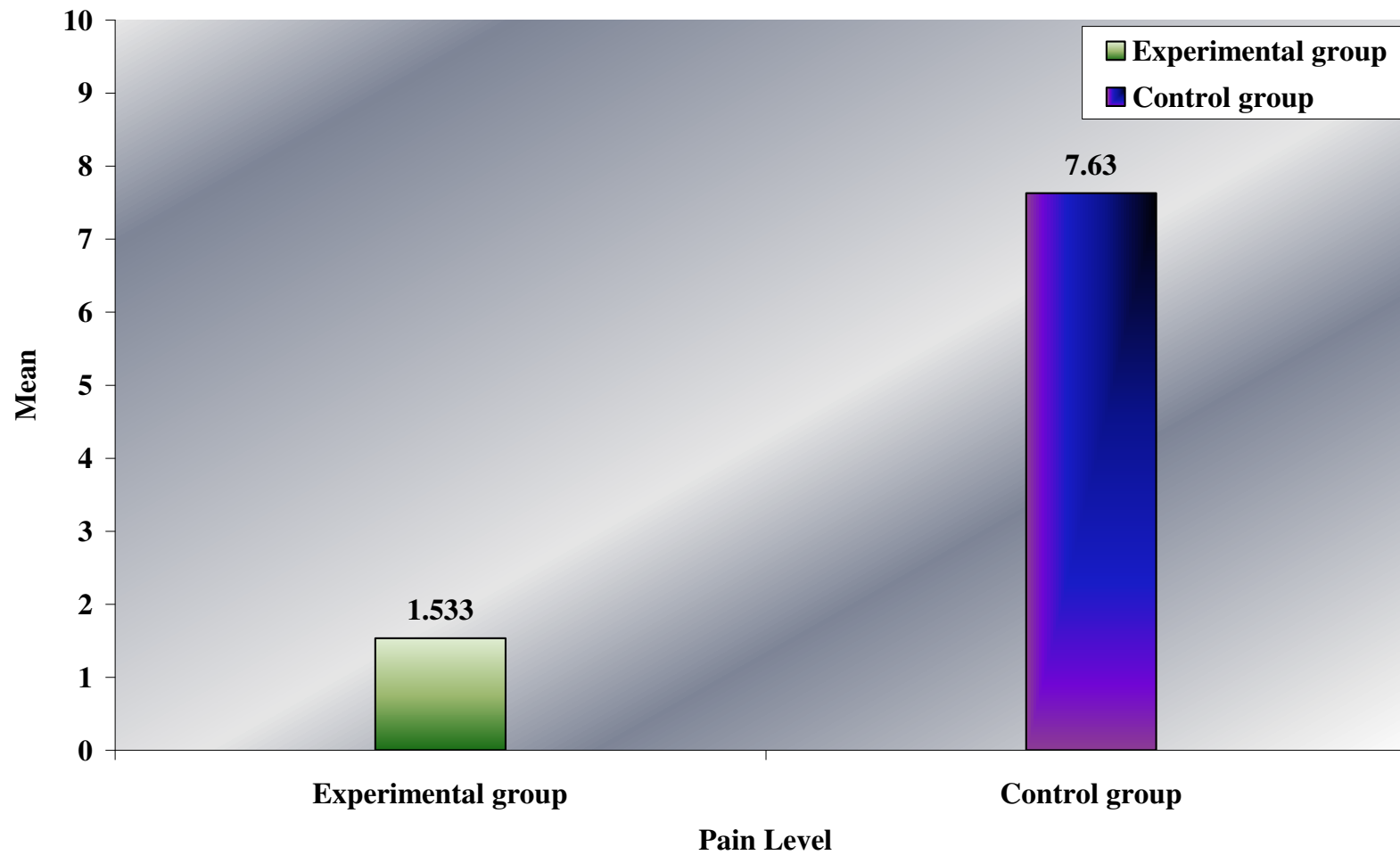
**Table. 2** Distribution of Statistical Value of Post Test Score for Experimental and Control Group Regarding Level of Pain During IM Injection Among 1-5 Year of Age Group Children

(N = 60)

S. No.	Pain Level	Mean	SD	't' value
1.	Experimental group	1.533	1.176	5.37*
2.	Control group	7.63	0.94	

\*significant at 0.05 level

Table. 2 shows that the calculated value of 't' value was 5.37 at  $p= 0.05$  level of significance which is greater than the expected table value 1.67 .This shows that there was a significant difference between the post test score of experimental and control group. This highlights that Vapocoolant spray has significant effect on reducing pain among children of age group 1-5 years, who is receiving IM injection.



**Figure. 13** Distribution of Statistical Value of Post Test Score for Experimental and Control Group Regarding Level of Pain During IM Injection Among 1-5 Year Age Group of Children

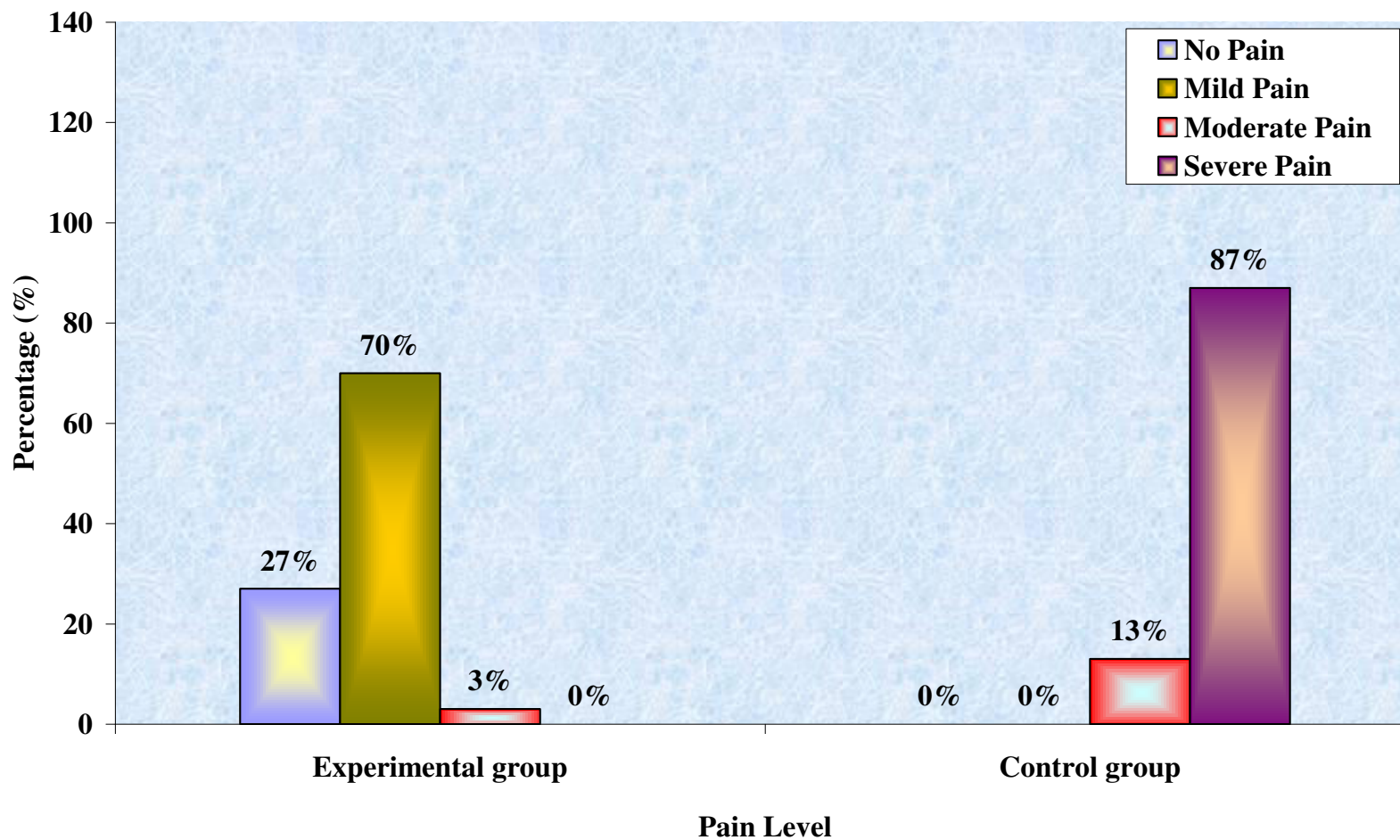
### SECTION - III

**Table. 3** Comparison of Pain Level in Experimental Group and Control Group  
According to FLACC Scale

(N = 60)

Pain Level	No Pain		Mild Pain		Moderate Pain		Severe Pain	
	f	%	f	%	f	%	f	%
Experimental group	8	27%	21	70%	1	3%	-	-
Control group	-	-			4	13%	26	87%

Table. 3 shows comparison of pain level in experimental and control group according to FLACC scale. Pain level in control group shows 0(0%) had no pain, 0(0%) had mild pain, 4(13%) had moderate pain and 26(87%) had severe pain. In experimental group the pain level shows 8(27%) had no pain, 21(70%) had mild pain, 1(3%) had moderate pain and 0(0%) had severe pain.



**Figure. 14** Comparison of Pain Level in Experimental Group and Control Group according to FLACC Scale

## SECTION - IV

**Table. 4** Association of Selected Demographic Variables with Post Test Pain Score of Experimental Group Among 1-5 Year of Age Group Children

(n=30)

S.No.	Demographic Variables	Above Mean	Below Mean	$\chi^2$
1.	<b>Age in years</b>			
	a) 1-2 years	9	9	0.824
	b) 3-4 years	6	4	
	c) 5 years	1	1	
2.	<b>Sex</b>			
	a) Male	7	10	0.195
	b) Female	7	6	
3.	<b>Education of the child</b>			
	a) Nil	10	12	2.063
	b) Pre primary	6	2	
4.	<b>Religion</b>			
	a) Hindu	14	12	1.133
	b) Christian	2	1	
	c) Muslim	0	1	
5.	<b>Education of father</b>			
	a) Illiterate	0	0	2.263
	b) Primary school	0	0	
	c) High school	0	2	
	d) Post high school/ Diploma	8	5	
	e) Graduate	8	7	

(Table 4 continues)

(Table 4 continued)

S.No.	Demographic Variables	Above Mean	Below Mean	$\chi^2$
6.	<b>Education of the mother</b> a) Illiterate b) Primary school c) High school d) Post high school/ Diploma e) Graduate	0 0 4 4 8	0 0 3 3 8	0.153
7.	<b>Occupation of the father</b> a) Professional b) Clerical c) Skilled d) Semiskilled e) Unemployed	4 4 8 0 0	4 3 6 1 0	1.303
8.	<b>Occupation of mother</b> a) Professional b) Clerical c) Skilled d) Semi-skilled e) Unemployed	3 2 2 1 7	4 1 2 1 7	0.476
9.	<b>Family income</b> a) Below ₹.5000/- b) ₹.5001-10,000/- c) ₹.10,001-20,000/- d) ₹.20,001 and above	0 1 10 5	0 2 4 8	3.479
10.	<b>Number of children in the family</b> a) 1 b) 2 c) 3 and above	7 8 1	10 4 0	1.809

(Table 4 continues)

(Table 4 continued)

S.No.	Demographic Variables	Above Mean	Below Mean	$\chi^2$
11.	<b>Birth order</b>			
	a) First	7	10	1.809
	b) Second	8	4	
	c) Third and above	1	0	
12.	<b>Area of residence</b>			
	a) Rural	6	6	0.086
	b) Urban	10	8	
13.	<b>Type of family</b>			
	a) Nuclear	13	10	0.402
	b) Joint	3	4	
14.	<b>Type of vaccine/injection</b>			
	a) DPT	3	4	3.246
	b) Hepatitis	5	1	
	c) MMR	2	3	
	d) Typhoid	3	4	
	e) Others	3	2	

Table. 4 shows the association of post test scores of pain during intramuscular injection in experimental group children with selected demographic variables by  $\chi^2$ . The variables like age, sex, education ,occupation of father, occupation of mother, family income, number of children, birth order, religion, education of mother, education of father, area of residence, type of family, type of vaccine/injection were not associated with post test score of pain in experimental group.



**Table. 5** Association of Selected Demographic Variables with Post Test Pain Score of Control Group Among 1-5 Year of Age Group Children

(n=30)

S.No.	Demographic Variables	Above Mean	Below Mean	$\chi^2$
1.	<b>Age in years</b>			
	a) 1-2 years	8	7	0.638
	b) 3-4 years	6	5	
	c) 5 years	3	1	
2.	<b>Sex</b>			
	a) Male	9	7	0.002
	b) Female	8	6	
3.	<b>Education of the child</b>			
	a) Nil	13	11	0.305
	b) Pre primary	4	2	
4.	<b>Religion</b>			
	a) Hindu	16	10	4.358
	b) Christian	0	0	
	c) Muslim	2	2	
5.	<b>Education of father</b>			
	a) Illiterate	0	0	3.125
	b) Primary school	1	1	
	c) High school	5	0	
	d) Post high school/ Diploma	2	4	
	e) Graduate	9	8	

(Table 5 continues)

(Table 5 continued)

S.No.	Demographic Variables	Above Mean	Below Mean	$\chi^2$
6.	<b>Education of the mother</b> a) Illiterate b) Primary school c) High school d) Post high school/ Diploma e) Graduate	0 1 7 3 6	0 1 3 4 5	1.323
7.	<b>Occupation of the father</b> a) Professional b) Clerical c) Skilled d) Semiskilled e) Unemployed	2 4 8 3 0	3 4 4 2 0	1.219
8.	<b>Occupation of mother</b> a) Professional b) Clerical c) Skilled d) Semi-skilled e) Unemployed	0 1 3 2 11	2 0 2 1 8	3.540
9.	<b>Family income</b> a) Below ₹.5000/- b) ₹.5001-10,000/- c) ₹.10,001-20,000/- d) ₹.20,001 and above	0 2 7 8	0 2 5 6	0.355
10.	<b>Number of children in the family</b> a) 1 b) 2 c) 3 and above	8 8 2	6 5 1	0.115

(Table 5 continues)

(Table 5 continued)

S.No.	Demographic Variables	Above Mean	Below Mean	$\chi^2$
11.	<b>Birth order</b>			
	a) I	7	7	0.502
	b) II	8	5	
	c) III and above	2	1	
12.	<b>Area of residence</b>			
	a) Rural	11	8	0.021
	b) Urban	6	5	
13.	<b>Type of family</b>			
	a) Nuclear	11	11	0.252
	b) Joint	6	2	
14.	<b>Type of vaccine/injection</b>			
	a) DPT	4	3	0.969
	b) Hepatitis	2	3	
	c) MMR	1	1	
	d) Typhoid	4	3	
	e) Others	6	3	

Table. 5 shows the association of post test scores of pain during intramuscular injection in control group children with selected demographic variables by  $\chi^2$ . The variables like age, sex, education, occupation of father, occupation of mother, family income, number of children, birth order, religion, education of mother, education of father, area of residence, type of family, type of vaccine/injection were not associated with post test score of pain in control group.

## **CHAPTER - V**

### **Results and Discussion**

The aim of the study was to assess the effectiveness of Vapocoolant Spray on reduction of pain among children of age group 1-5 years undergoing intramuscular injection. Quasi-experimental approach, a subtype of quantitative approach was used for the present study. This study uses post test only design. The results and the discussion of the study were based on the findings obtained from the statistical analysis and interpretation.

#### **The First Objective of the Study was to Provide Vapocoolant Spray Before Intramuscular Injection to the Experimental Group**

The sample for the present study comprises of 60 children, 30 children for experimental group and 30 children for control group .The samples were equally assigned to control and experimental group. The investigator assessed the pain of the children after IM injection. For the experimental group Vapocoolant spray was administered 10 seconds before the IM injection, and then the pain was assessed by using FLACC scale.

A similar study was conducted by Eun Kyong Choi et.al (2008) by a randomized, controlled study to test the efficacy of vapocoolant spray to decrease the symptoms associated with pain undergoing heel stick and intramuscular injection and compare the pain relief effect of oral glucose including sixty newborns. Group 1 was heel sticked, Group 2 was intramuscular injected, Group A did not received any treatment, Group B received 30% glucose solution orally, Group C received

vapocoolant spray. Signs and symptoms associated with pain at heel stick and intramuscular injection were measured by using premature Infant Pain Profile (PIPP) scale. The mean PIPP score were significantly lower than control and concluded that the use of vapocoolant spray was effective for reducing pain during painful procedure in the neonatal intensive care units.

### **The Second Objective of the Study was to Assess the Effectiveness of Vapocoolant Spray During Intramuscular Injection Among Experimental Group**

The post test score for experimental group was 1.533 and for control group was 7.63 and the calculated 't' value is 5.37 at  $p=0.05$  level of significance which is greater than the expected table value 1.67. This highlights that Vapocoolant spray has significant effect on reducing pain among children of age group 1-5 years, who is receiving IM injection.

A similar study was conducted by Evelyn Cohen Reis (1997) done a randomized, controlled clinical trial to compare the efficacies of two pain management methods in reducing immediate immunization pain and distress in school-aged children by using eutectic mixture of local anesthetics (EMLA) cream and Vapocoolant spray. Children were randomized to one of three treatment groups with EMLA cream and distraction, second group with Vapocoolant spray and distraction and the third group with distraction alone (control). The investigator measured cry duration and the number of pain behaviors using the Observational Scale of Behavioral Distress. Both EMLA and spray were significantly better than control group and concluded that vapocoolant spray significantly reduces immediate injection pain compared with distraction alone and is equally effective as, less expensive, and faster-acting than EMLA cream.

### **The Third Objective of the Study was to Assess Level of Pain During Intramuscular Injection in Control Group**

In this study pain level in control group, shows 0(0%) had no pain, 0(0%) had mild pain, 4(13%) had moderate pain, 26(87%) had severe pain. In experimental group, the pain level shows 8(27%) had no pain, 21(70%) had mild pain, 1(3%) had moderate pain, 0(0%) had severe pain. This reveals that there was pain during intramuscular injection in control group.

Romano. C. L (2005) conducted a study to assess the effectiveness of blunt pin application to reduce pin prick pain during intramuscular and subcutaneous injection in 212 patients. Patients were randomly assigned to 2 groups: experimental (n=106) and control group (n=106). Experimental group received injection with the application of blunt pins and control group with a placebo device. Pain was assessed with visual analogue scale. The study revealed that control group had more pain than experimental group.

### **The Fourth Objective of the Study was to Compare the Level of Pain Among Experimental and Control Group**

The post test mean score of the experimental group was 1.533. The post test mean score of the control group was 7.63. This highlights that there was a significant difference between the post test score of experimental and control group. This reveals that Vapocoolant spray has significant effect on reducing pain among children of age group 1-5 years, who is receiving IM injection.

These findings were supported by Marayam Modarres, et.al (2013) conducted a randomized clinical trial. A sample of full term neonates was randomly allotted in to

2 groups. The experimental group and the control group. Neonates in the experimental group were breast fed 2 minutes before, during and after the hepatitis B immunization and the control group were held on mothers arm, but not fed. Pain was assessed by using Douleur Aigue du Nouveau-ne (DAN) scale. The study revealed that experimental group has reduced pain than control group.

#### **The Fifth Objective of the Study was to Associate the Level of Pain with Selected Demographic Variables Among Experimental and Control Group**

The demographic variables like age, gender, education of the child ,occupation of father, occupation of mother, family income, number of children, birth order, religion, education of mother, education of father, area of residence, type of family, type of vaccine/injection was assessed and were associated with post test score of experimental and control group by using chi square test. The result revealed that there was no association between pain and selected demographic variables both in experimental and control group.

## **CHAPTER - VI**

### **Summary, Conclusion, Nursing Implications, Limitations and Recommendations**

#### **Summary**

The study was conducted to assess the effectiveness of Vapocoolant Spray on reduction of pain among children of age group 1-5 years undergoing intramuscular injection in selected hospital at Coimbatore.

#### **The Following Objectives Were Set for the Study**

- To provide Vapocoolant spray before intramuscular injection to the experimental group.
- To assess the effectiveness of Vapocoolant spray during intramuscular injection among experimental group.
- To assess level of pain during intramuscular injection in control group.
- To compare the level of pain among experimental and control group.
- To associate the level of pain with selected demographic variables among experimental and control group.

#### **The Alternative Hypothesis Set for the Study**

There will be significant difference in the level of pain among children receiving IM injection between experimental and control group.

#### **Major Findings of the Study were as Follows**

- The post test mean score of the experimental group was 1.533.
- The post test mean score of the control group was 7.63.



- The obtained 't' value for comparison of post test score of pain at ( $p < 0.05$ ) level was 5.37.
- The post test result for experimental group revealed that 8 (27%) had no pain, 21(70%) had mild pain, 1(3%) had moderate pain and 0(0%) had severe pain.
- The post test result for control group revealed that 0 (0%) had no pain, 0(0%) had mild pain, 4(13%) had moderate pain and 26 (87%) had severe pain.
- There was no association between post test score of pain with demographic variables among experimental and control group.

## Conclusion

The main focus of the study was to assess the effectiveness of Vapocoolant Spray on reduction of pain among children of age group 1-5 years undergoing intramuscular injection in selected hospital at Coimbatore. The mean post test score for experimental group was lower than the mean post test score for the control group. The finding shows that Vapocoolant spray was effective in reducing pain among children of age group 1-5 years undergoing intramuscular injection so the alternative hypothesis was accepted.

The  $\chi^2$  was used to find out the association between selected demographic variables with pain among children of age group 1-5 years undergoing intramuscular injection. The result revealed that there was no association between selected demographic variables with pain among children in experimental group and control group.

## **Nursing Implications**

The findings of the study have implications on nursing education, nursing practice, nursing administration, and nursing research.

### **Nursing Education**

- The curriculum of nursing education should enable student nurses to equip themselves within the knowledge of using Vapocoolant spray. The nursing education should give more importance to the application of theory into practice.
- In-service education to nurses and paramedical can be organized with advanced modalities to reduce pain among children.
- Periodic seminars and group discussions can be arranged regarding care of children with injection pain and newer modalities to control the pain.
- Nursing personal working in various health setting should be given in-service education and training to update their knowledge and skills for reducing level of pain.
- The use of Vapocoolant spray can be taught to all the nurses who work in pediatric department to upgrade their knowledge on diversion among children of age group 1-5 years undergoing IM injection / IV cannulation.

### **Nursing Practice**

- The use of Vapocoolant spray can be emphasized by the staff nurse's in pediatric setting to reduce the level of pain among children.
- The findings of the current study can be kept as baseline for providing diversion to children undergoing IM injection.

- Teaching programme can be conducted for parents regarding various methods of pain reduction.
- The application of Vapocoolant spray can be incorporated in nursing practice by making nurses aware about the fact that Vapocoolant spray will reduce pain perception.
- The study helps the nurses to develop specific skill in using Vapocoolant spray as a pain relieving measure among children of age group of 1-5 years undergoing IM injection.

### **Nursing Administration**

- The health care system is responsible to provide parents and care givers educational services as an integral part of high qualities and cost effectiveness.
- The nurse can become an effective coordinator and leader by introducing divertional therapy in pediatric settings.
- Administrators should organize in-service educational programmes, refresher courses and workshops for nurses and encourage them to participate in these activities.
- Leader in nursing are challenged to undertake health needs of children.
- The administrator should take part in health policy making, developing portal procedures for parent's education.

### **Nursing Research**

- The essence of research is to build up body of knowledge in nursing as it is an evolving profession. The effectiveness of the research can be made by further implication of the study.

- Nurse researcher can do a research on the community.
- Can be used for evidence based nursing practice as a rising trend.
- The study findings can be added to the research review regarding the use of Vapocoolant spray.
- One of the main aim of nursing research is to contribute knowledge to the nurses to expand and broaden the scope of nursing. The study findings can be kept as the baseline data and further research can be conducted in same setting, which is possible only if nurses are taking initiative to conduct further research.

### **Limitations**

- The study included only children of age group 1-5 years who are receiving injection including immunization in Masonic hospital at Coimbatore.
- The route of injection that is considered for the study is IM.
- Time duration limited to 1 month.
- The size of the sample was small to draw generalizations.

### **Recommendations**

- The same study can be conducted in different setting such as hospitals, community centers, clinics etc.
- The study can be conducted on children of age group 1-5 years undergoing other procedural pain.
- The study can be done in large samples with different age group and different setting to have wider applicability.
- The study can be conducted using other divertional therapy.
- The study can be conducted as a true experimental study.

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## ABSTRACT

**Statement of the Problem :** A study to assess the effectiveness of Vapocoolant Spray on reduction of pain among children of age group 1-5 years undergoing intramuscular injection in a selected hospital at Coimbatore. **Objectives :** (a) To provide Vapocoolant spray before intramuscular injection to the experimental group (b) To assess the effectiveness of Vapocoolant spray during intramuscular injection among experimental group. (c) To assess level of pain during intramuscular injection in control group. (d) To compare the level of pain among experimental and control group. (e) To associate the level of pain with selected demographic variables among experimental and control group. **Methodology :** The research design selected for the study was quasi experimental research design (post test only design). Sample size for this study was 60. Pain level was assessed by using FLACC scale and demographic variables were used to collect data. **Results :** Descriptive and inferential statistics were used to analyze the data. The independent 't' test was performed to compare the post test value of experimental and control group. The calculated value of 't' test was 5.37 which is greater than the table value. Hence the stated hypothesis  $H_1$  was accepted. **Conclusion :** The study revealed that the application of vapocoolant spray was effective in reducing pain during intramuscular injection among children of age group 1-5 years.



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**To**

**Through**

**The Principal,**  
PPG College of Nursing  
Coimbatore – 35.

Respected Sir,

**Sub :** Seeking permission for conducting research study

I am a student of M.Sc Nursing in PPG College of Nursing. Our college is affiliated to the Tamilnadu Dr. M. G. R Medical University, Chennai. I have taken the specialization in Child Health Nursing.

**Topic : A STUDY TO ASSESS THE EFFECTIVENESS OF  
VAPOCOOLANT SPRAY ON REDUCTION OF PAIN AMONG  
CHILDREN OF AGE GROUP 1-5 YEARS UNDERGOING  
INTRAMUSCULAR INJECTION IN A SELECTED HOSPITAL AT  
COIMBATORE**

I request you to kindly permit me to conduct my study in hospital. Hope you will consider my requisition and do the needful.

Thanking you,

Yours sincerely,

Date :

Place : Coimbatore

## **Requisition Letter for Content Validity**

From

M.Sc (N) II Year,  
PPG College of Nursing,  
Coimbatore – 35.

**To**

**Through : Principal, PPG College of Nursing**

Respected Sir/Madam,

**Sub : Requisition for expert opinion and suggestion for content validity of tool**

I am a student of M.Sc (N) II year, PPG College of Nursing affiliated to the Tamilnadu Dr. M. G. R. Medical University, Chennai. As a partial fulfillment of the M.Sc (N) programme. I am conducting

**A STUDY TO ASSESS THE EFFECTIVENESS OF VAPOCOOLANT  
SPRAY ON REDUCTION OF PAIN AMONG CHILDREN OF AGE GROUP  
1-5 YEARS UNDERGOING INTRAMUSCULAR INJECTION IN A  
SELECTED HOSPITAL AT COIMBATORE**

Herewith I have enclosed the developed tool for content validity and for the expert opinion and possible solution. It would be very kind of you to return the same as early as possible.

Thanking you,

Yours faithfully,

**PPG College of Nursing**  
**Format for the Content Validity**

Name of the expert :

Address :

Total content for the tool :

Kindly validate each tool and tick wherever applicable

<b>S.No</b>	<b>No. of Tool/Section</b>	<b>Strongly Agree</b>	<b>Agree</b>	<b>O.K</b>	<b>Not Applicable</b>	<b>Need Modification</b>	<b>Remarks</b>

Remarks

Signature of the Expert with Date

## SECTION- I

### Demographic Variables

#### Instructions

Read the following questions carefully and give (✓) in a given boxes for correct answer.

Sample Number:.....

#### 1. Age in years

- a) 1-2 years ☐
- b) 3-4 years ☐
- c) 5 years ☐

#### 2. Sex

- a) Male ☐
- b) Female ☐

#### 3. Education of the child

- a) Nil ☐
- b) Pre primary ☐

#### 4. Religion

- a) Hindu ☐
- b) Christian ☐
- c) Muslim ☐



**5. Education of father**

- a) Illiterate ☐
- b) Primary school ☐
- c) High school ☐
- d) Post high school/diploma ☐
- e) Graduate ☐

**6. Education of the mother**

- a) Illiterate ☐
- b) Primary school ☐
- c) High school ☐
- d) Post high school/diploma ☐
- e) Graduate ☐

**7. Occupation of father**

- a) Professional ☐
- b) Clerical ☐
- c) Skilled ☐
- d) Semi-skilled ☐
- e) Unemployed ☐

**8. Occupation of mother**

- a) Professional ☐
- b) Clerical ☐
- c) Skilled ☐
- d) Semi-skilled ☐

e) Unemployed ☐

**9. Family income**

a) Below ₹. 5000/- ☐

b) ₹.5001-10,000/- ☐

c) ₹.10,001-20,000/- ☐

d) ₹.20,001 and above ☐

**10. Number of children in the family**

a) 1 ☐

b) 2 ☐

c) 3 and above ☐

**11. Birth order**

a) First ☐

b) Second ☐

c) Third and above ☐

**12. Area of residence**

a) Urban ☐

b) Rural ☐

**13. Type of family**

a) Joint ☐

b) Nuclear ☐

**14. Type of vaccine/injection**

- a) DPT ☐
- b) Hepatitis ☐
- c) MMR ☐
- d) Typhoid ☐
- e) Others ☐

## SECTION - II

### FLACC Scale for Assessment of Pain Among Children

Criteria	Score 0	Score 1	Score 2
<b>Face</b>	No particular expression or smile	Occasional grimace or frown, withdrawn, uninterested	Frequent to constant quivering chin, clenched jaw
<b>Legs</b>	Normal position or relaxed	Uneasy, restless, tense	Kicking, or legs drawn up
<b>Activity</b>	Lying quietly, normal position, moves easily	Squirming, shifting back and forth, tense	Arched, rigid or jerking
<b>Cry</b>	No cry (awake or asleep)	Moans or whimpers; occasional complaint	Crying steadily, screams or sobs, frequent complaints
<b>Consolability</b>	Content, relaxed	Reassured by occasional touching, hugging or being talked to, distractible	Difficult to console or comfort

The possible maximum score was 10

The possible minimum score was 0

### **Grading**

<b>Scores</b>	<b>Interpretations</b>
0	Relaxed and comfortable
1-3	Mild pain
4-6	Moderate pain
7-10	Severe pain

பகுதி : I

நேர்காணல் படிவம்

குறிப்பு

கீழ்க்கண்ட வினாக்களை சரியாக படித்து கீழே கொடுக்கப்பட்டுள்ள  
கட்டத்தில் ☒ கொடுக்கவும்

மாதிரி எண் : \_\_\_\_\_

1. குழந்தையின் வயது

- அ. 1-2 வயது ☐
- ஆ. 3-4வயது ☐
- இ. 5 வயது ☐

2. பாலினம்

- அ. ஆண் ☐
- ஆ. பெண் ☐

3. குழந்தையின் கல்வித்தகுதி

- அ. படிப்பறிவுஇல்லாதவர் ☐
- ஆ. தொடக்கக் கல்வி ☐

4. மதம்

- அ. இந்து ☐
- ஆ. கிறிஸ்தவம் ☐
- இ. இஸ்லாமியர் ☐

5. தந்தையின் கல்வி தகுதி

- அ. படிப்பறிவில்லாதவர் ☐
- ஆ. ஆரம்பநிலைக்கல்வி ☐
- இ. உயர்நிலைப்பள்ளி ☐
- ஈ. மேல் நிலைப் பள்ளி / பட்ட சான்றிதழ் பட்டம் ☐
- உ. பட்டப்படிப்பு ☐

6.தாயின் கல்வி தகுதி

- அ. படிப்பறிவில்லாதவர் ☐
- ஆ. ஆரம்பநிலைக்கல்வி ☐
- இ. உயர்நிலைப்பள்ளி ☐
- ஈ. மேல் நிலைப் பள்ளி / பட்ட சான்றிதழ் பட்டம் ☐
- உ. பட்டப்படிப்பு. ☐

7.தந்தையின் தொழில்

- அ. தொழில்நுட்பம் சம்பந்தமான வேலை ☐
- ஆ.எழுத்தர் வேலை ☐
- இ. திறமையான வேலை ☐
- ஈ. ஓரளவு திறமையான வேலை ☐
- உ. வேலையில்லாதவர் ☐

8. தாயின் தொழில்

- அ. தொழில்நுட்பம் சம்பந்தமான வேலை ☐
- ஆ.எழுத்தர் வேலை ☐
- இ. திறமையான வேலை ☐
- ஈ. ஓரளவு திறமையான வேலை ☐
- உ. வேலையில்லாதவர் ☐

9. குடும்ப வருமானம்

அ. ₹.5000-க்கு கீழ்

☐

ஆ. ₹. 5001- 10000

☐

இ. ₹. 10001-20000

☐

ஈ. ₹. 20001 மற்றும் மேல்

☐

10. குழந்தைகளின் எண்ணிக்கை

அ. 1

☐

ஆ. 2

☐

இ. 3 மற்றும் அதற்கு மேல்

☐

11. பிறப்பு வரிசை

அ. I

☐

ஆ. II

☐

இ. III மற்றும் அதற்கு மேல்

☐

12. வசிக்கும் பகுதி

அ. நகரம்

☐

ஆ. கிராமம்

☐

13. குடும்ப வகை

அ. கூட்டுக்குடும்பம்

☐

ஆ. தனிக்குடும்பம்

☐



14. தடுப்பு மருந்தின் வகை

அ. டி.பி.டி

☐

ஆ. மஞ்சள் காமாலைக்கு ஏதிரான தடுப்பூசி

☐

இ. எம்.எம்.ஆர்

☐

ஈ. டைப்பாய்டு

☐

உ. மற்றவை

☐

# **PROTOCOL FOR VAPOCOOLANT SPRAY**

## **Introduction**

Ethyl chloride is a Vapocoolant. It is a skin refrigerant intended for topical application to control pain, associated with injections, minor surgical procedures and the temporary relief of minor sports injuries.

## **Definition**

It is a volatile explosive liquid (under increased pressure); when sprayed on skin, produces local anesthesia by superficial freezing, but also is a potent inhalation anesthetic.

**-Stedman's Medical Dictionary (2000)**

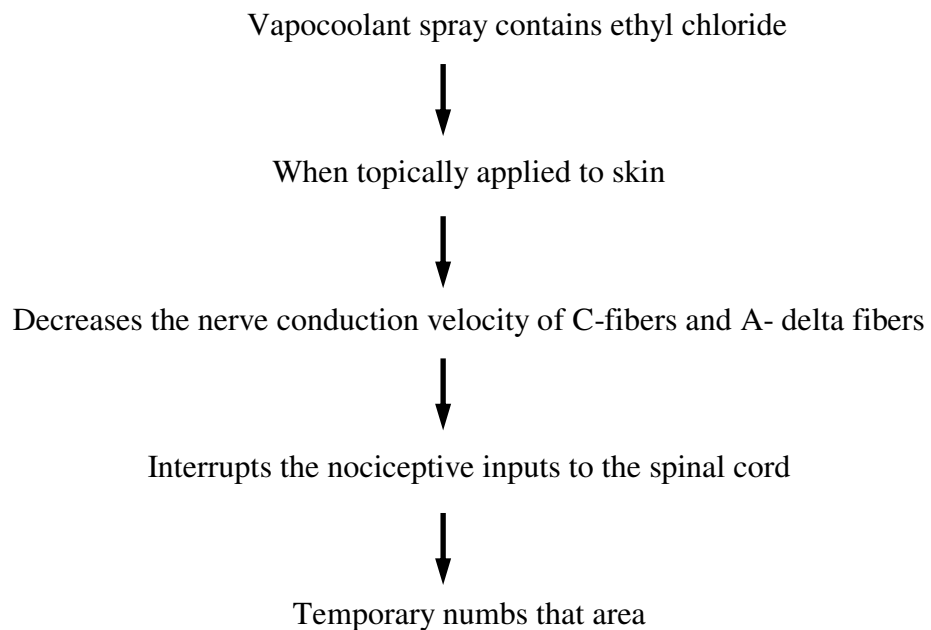
It is a topical cold application spray.

**-Mosby's Dictionary (2005)**

## **Indication and Uses**

- Used as topical applicant to control pain associated with injections, minor surgical procedures.
- Phlebotomy.
- It also helps to relieve deep muscle pain, when used with muscle stretching technique.
- Local anesthesia for intravenous catheter insertion.
- Temporary relief of minor sports injuries.

## **Physiology of Action**



## **Side Effects**

A very serious allergic reaction to this drug is unlikely. Symptoms of allergic reaction includes

- Rash.
- Itching and swelling(face, tongue, throat)

## **Contra Indication**

Ethyl chloride is contra indicated in individual with a hypersensitivity to it.

## **Adverse Reaction**

Cutaneous sensitization may occur, but appear to be extremely rare. Freezing can occasionally alter pigmentation.

## **Precautions**

- Ask about allergic reaction to medication.
- Ethyl chloride is flammable and should never be used in the presence of an open flame or electrical cautery equipment.
- Avoid inhalation of ethyl chloride as it may produce narcotic and general anesthetic effect, deep anesthesia or fatal coma with respiratory or cardiac arrest.
- This is used only as a topical medication.

## **Articles Required**

- Bowl
- Cotton balls-2
- Betadine solution
- Vaseline
- Vapocoolant spray
- FLACC scale

## **Pre Procedure**

Before the procedure the parents are explained about the Vapocoolant spray, its indication, uses and action. After getting oral consent from parents, Vapocoolant spray is introduced to the child.

## **Procedure**

- Provide supine position to the child.
- Perform test dose to detect any allergies.
  - Wash hands.

- Swab the lateral aspect of the arm with betadine solution.
  - Apply petroleum jelly (Vaseline) to the surrounding area.
  - Spray vapocoolant until the skin starts to turn white/numb.
- Wait for 5 minutes. If no allergic reactions perform the procedure.
  - Locate the site for injection, preferably vastus lateralis (right or left leg).
  - Wash hands.
  - Swab the area with betadine solution.
  - Apply Vaseline to the surrounding area.
  - Hold the container 12-18 inches away from the muscle and then spray in a sweeping motion for 4-10 seconds.
  - Spray until the skin starts to turn white or numb.
  - Immediately do the procedure since the numbing effect of ethyl chloride only lasts for a few seconds to a minute.

## **Conclusion**

Injectons are stressful for many children; until new approaches are developed, systematic use of available techniques can significantly reduce the burden of distress associated with these procedures. Ethyl chloride is a cooling substance that is applied to the skin to numb the area. It is a skin refrigerant which produces local anesthesia by superficial freezing, and provides cooling effect on the skin.

## **LIST OF EXPERTS**

**1. Prof. SUGANTHI, M.Sc,**

Department of Pediatrics,  
Sri Ramakrishna College of Nursing,  
Coimbatore.

**2. Prof. VIJAYALAKSHMI, M.Sc,**

Department of Pediatrics,  
KG College of Nursing,  
Coimbatore.

**3. Prof. EMERENSIA, M.Sc,**

Department of Pediatrics,  
R V S College of Nursing,  
Coimbatore.

**4. Prof. LIZY RAVENDRAN, M.Sc,**

Department of Pediatrics,  
G E M College of Nursing,  
Coimbatore.

**5. Prof. THENMOZHI ,M.Sc,**

Department of Pediatrics,  
Texcity College of Nursing,  
Coimbatore.

**A STUDY TO ASSESS THE EFFECTIVENESS OF VAPOCOOLANT  
SPRAY ON REDUCTION OF PAIN AMONG CHILDREN OF AGE  
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